INDIAN DRUG MANUFACTURERS' ASSOCIATION

Indian APIs & Formulations for Global Healthcare

ANNUAL REPORT

59th

2019-20

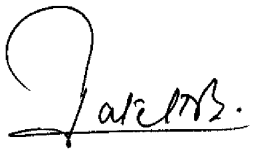
Delivering Healthcare...to the World !!

N O T I C E

The 59th Annual General Meeting of the Indian Drug Manufacturers' Association will be held on **Wednesday, 31st March 2021 at 4:30 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 2019-20
3. To adopt the audited Statement of Accounts for the year ended 31st March 2020
4. To appoint auditors for the year 2020-21
5. Any other business with the permission of the Chair.



Daara B Patel
Secretary - General

Date: March 17, 2021

Note: *Members who need clarifications or details with regard to the Agenda for the meeting are required to write to IDMA office specifying the clarification required by them on or before 26th March 2021.*

IDMA EXECUTIVE COMMITTEE 2020

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* **SAIMIRRA INNOPHARM PVT. LT D** 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

JAY MEHTA *(resigned in November 2020)*
President – Global Business (Russia / CIS) & CRAMS
J.B. Chemical & Pharmaceuticals Ltd.
Cnergy IT Park, Unit A, 8th Floor,
Appa Saheb Marathe Marg, Prabhadevi,
Mumbai - 400 025

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. LT D.
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
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CHIRAG HASMUKHLAL DOSHI
Director
Yash Medicare Pvt. Ltd.
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Ellisbridge, Ahmedabad – 380 006.

DR. AMIT RANGNEKAR
Vice President
Centaur Pharmaceuticals
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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. DINESH DUA
CEO & Director
Nectar Lifesciences Ltd.
S.C.O. 38-39, Sector 9D,
Chandigarh 160 009

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.
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Andheri (East), Mumbai – 400 059.

DR MILIND JOSHI
President – Global Regulatory Management
J. B. Chemicals & Pharmaceuticals Ltd
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DR. R. K. SANGHAVI
Consultant – Neuro Marketing
Vilco Labs Pvt. Ltd.
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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.
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HARSHIT MANILAL SAVLA
Joint Managing Director
Aarti Drugs Ltd.
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J. L. SIPAHIMALANI
Managing Partner
Chem Med Analytical Laboratories
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Mumbai - 400 018.

KAMLESH C. PATEL
Managing Director
West-Coast Pharmaceutical Works Ltd.
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KUNAL N GANDHI
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MAYANK JASHWANTLAL SHAH
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MOHAN BABULAL JAIN
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NANDAN M CHANDAVARKAR
Joint Managing Director
FDC Limited
C – 3, Sky Vistas, 106-A J P Road,
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NEHA THAKORE
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Gauri Studio Compound,
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Mumbai - 400 069.

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Managing Director
Marvel Drugs Pvt. Ltd.
20, Nagin Mahal, 5th Floor, 82, V.N. Road,
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Director
Gufic Biosciences Ltd.
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Vile Parle (East), Mumbai-400 057.

PRANABH MODY *(resigned in November 2020)*
President
J. B. Chemicals & Pharmaceuticals Ltd.
Cnergy IT Park, Unit A, 8th Floor,
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RAJASEKHAR AKKARAJU
Regional Director & Head - Quality
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RAVI UDAYA BHASKAR
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SHASHIKANT DAMODAR JOAG
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Synergy Pharma Formulations India Pvt. Ltd.
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S. K. SINGH
Managing Director
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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
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SAMITA H. AIYER
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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
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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

DR CHRISTIANE HAMACHER
Biocon Biologics India Ltd.
Biocon House, Semicon Park,
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SOHAN DADHICH
Managing Director
KLM Laboratories Pvt. Ltd.
304-306 Union Trade Centre, Near Apple Hospital,
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AJAY BHARADWAJ
Chief Executive Officer
Anthem Bioscience Privat E Limited
No 49, Canara Bank Road,
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AJAY KUMAR DESAI
VP, Accounts & Finance
Alembic Pharmaceuticals Limited
2nd Floor, Prime Corporate Park, Behind ITC Grand
Maratha-Sheraton, Sahar Road, Andheri (East),
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MR. ANIL KUMAR SRIVASTAVA
(Vice President & SBU Head)
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.
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J. J. SHAH
Chairman
Oceanic Pharmachem Pvt Ltd
FC/B-1 (Extn.), Mohan Co-operative
329, A-Z Industrial Estate, G. Kadam Marg,
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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,
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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.

PATRON MEMBERS

DR. VIVEK V. PALKAR
Chairman & Managing Director
Nivedita Chemicals Pvt. Ltd.
AnekPrayogPvt. 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,
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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 LABORATO RIES PVT. LT D.
Inga House, Mahakali Road, Andheri (E),
Mumbai - 400 093.

J. B. MODY *(Expired on 21 July 2020)*
Chairman & Managing Director
J. B. Chemicals & Pharmaceuticals Ltd.
Cnergy IT Park, Unit A1, 8th Floor,
Appa Saheb Marathe Marg,
Prabhadevi, Mumbai 400 025.

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

GUJARAT STATE BOARD
Chairman

DR VIRANCHI SHAH
Director
Saga Laboratories
Survey 198/2-3, Chachrawadi, Besides
Claris, Sarkhej Bawla Highway,
Changodar,Ahmedabad - 382 210.

MILAN R PATEL (W.E.F 1st June 2020)
Jt. Managing Director
Troikaa Pharmaceuticals Ltd.
'Commerce House-1', Satya Marg,
Bodakdev, Ahmedabad - 380 054, Gujarat

Hon. Secretary	**DR. SHRENIK K SHAH** *Hon. Secretary* **Montage Laboratories Pvt. Ltd.** At-Dhandha, Idar Road, Himatnagar 383 001.
	SUMIT JAGDISH AGRAWAL (W.E.F 1st June 2020) *Managing Director* **Ishita Pharmaceuticals** 401, 3rd Eye II, Opp. Parimal Garden, C G Road, Ahmedabad - 380 006, Gujarat.
Executive Secretary	**MR 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
Executive Secretary
IDMA Tamil Nadu Kerala & Puducherry State Board
Block-D1, BaidMetha 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

UTPAL MOITRA
Director
Emcee Pharmaceuticals P. Ltd.
DA-201, Sector – I,
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Kolkata – 700 064.

SHIV SAGAR TEWARI (W.E.F 1st April 2020)
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 CHAIRMAN 2020

Sr. Nos.	Committees	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.	**Mr.Ram Sundaram** 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

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S RANGANATHAN
Assistant Manager (Administration)

59th Annual Report 2019-20

Dear Member,

The 59th Annual Report covers the learnings of the New Normal that we all have experienced during this Covid-19 Pandemic throughout the year. I have always believed that TEAMWORK works. Our entire Team consisting of our National President, Mr. Mahesh Doshi, Past Presidents, Office Bearers, specially our Hon. General Secretary, Dr George Patani, our very active State Boards, the Chairmen, Vice-Chairmen & Members of various Committees, our Consultants / Advisors and our Staff at Head Office as well as Delhi Office rose to the occasion and managed the show in an exemplary manner.

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.

This was possibly the first time in the history of our Association and the Pharma Industry that we have worked closely and shoulder to shoulder with our Parent Ministry, i.e. Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals as well as the other concerned Ministries. We have proved to the Nation that by close and regular co-ordiantion between Industry Associations and the Ministries – the impossible could be achieved.

I remember with joy and enthusiasm, the invitation our National President and I received from the officials of FDA Maharashtra as well as Department of Pharmaceuticals for a video conference with our Honourable Prime Minister Shri Narendra Modi on 21st March 2020 at Mantralaya, Mumbai. The Prime Minister spoke very highly of the Pharma Industry and mentioned that the entire world is looking upto India during this crisis for supplying Covid-19 related medicines. A commitment was made to the Prime Minister by all the Associations & Industry Heads that we would ensure uninterrupted supply of medicines to our Country as well as Globally, however, we would need Government Support.

With regular interactions with Dr P D Vaghela (Retd.), Secretary, Dept. of Pharmaceuticals, Shri Navdeep Rinwa, Jt. Secretary, Dept. of Pharmaceuticals, various State FDA Officials & State Governments, the DCG(I) & his dedicated team, the CDSCO, the Police Department, officials of AIOCD and the rest, we achieved a great feat – THE CAPACITY UTILIZATION IN OUR FACTORIES ROSE FROM A MEAGRE 25-30% DURING MARCH / APRIL 2020 TO 60-80% DURING MAY / JUNE 2020. In fact some companies touched 100% capacity. We managed this by increasing the availability of raw materials, packing materials & requisite manpower not to forget the supply chain & distribution channels.

This was also for the first time that the heads of three major Associations – Indian Pharmaceuticals Alliance (IPA), Organisation of Pharmaceutical Producers of India (OPPI) and IDMA had a con call every day for almost three-four months to discuss and jointly address issues of the industry.

CDSCO Workshop at Mumbai on 3 February 2020

*As desired by Dr V G Somani, DCG(I) IDMA had organised the '**Workshop on E-Governance Initiatives of CDSCO**' on Monday, 3rd February 2020 at Sunville, Worli, Mumbai jointly with CDSCO and CDAC. The Workshop was a huge success with 450+ participants comprising of over 375 delegates and 75 officials from CDSCO and FDAs of Maharashtra, Madhya Pradesh, Goa, Uttarakhand, etc.*

IDMA Bulletin and Indian Drugs digital versions

Due to the nationwide lockdown, printing presses were not allowed to run, as they are not considered essential services. Hence we could not print our weekly publication IDMA Bulletin and monthly Indian Drugs. However, we successfully released digital issues of these publications. The digital copies of IDMA Bulletin & Indian Drugs are being emailed to all Members and also uploaded on IDMA website.

Problem-solving Group formed in Maharashtra

Immediately after the nationwide lockdown was announced, Maharashtra Government formed groups comprising of Government and Industry representatives with Mr. Sanjiv Jaiswal, IAS heading the Group. This Group has been meeting via Video Conferencing almost every day and addressing issues received on Whatsapp to sort out problems of manufacturing services, logistics etc pertaining to Maharashtra. Mr Mahesh Doshi, Mr Daara Patel, Dr. George Patani, Mr Bharat Shah and Mr B G Barve represented IDMA in the Group that also included other Associations like IPA and OPPI. The Group discussed matters on a day-to-day basis to address the issues in manufacturing, logistics, RM/PM matters, employee attendance etc. in the State.

IDMA-Invest India - Joint Meeting with MoS C&F, Shri Mansukh Mandaviya

*An Interactive Video Conference with Hon'ble Minister Shri Mansukh Mandaviya was organised by Invest India on 14 July 2020. The theme was "**Strengthening India's Pharmaceutical Industry Post COVID-19".** Invest India is a Government organisation working in Ministry of Commerce as the National Investment Promotion and Facilitation Agency of India and acts as the first point of reference for investors in India. We discussed a number of issues broadly relating to the promotion of the following:*

(a) API industry in India, replacing imports;

(b) Exports of API and Formulations from India, further strengthening the position;

(c) R&D helping the industry to add value to its operations;

(d) Investments in Indian pharma industry, through path breaking steps such as Regulatory simplification, decriminalization of Drugs & Cosmetics Act and rules as well as Environment Act, easing of Price Control measures, Financing issues, and other ease of doing business initiatives.

Chairmen of various IDMA Committees, Past Presidents and domain experts participated and discussed a number of issues. A detailed Note to explain in depth issues relating to Regulatory and Quality matters was forwarded earlier to the Minister along with the main points of our presentation. We complimented the Hon'ble Minister for spearheading the PLI Schemes for API and setting up of Bulk Drug Parks. The Hon'ble Minister provided a summary of the vision and mission of the Government in further boosting Pharmaceutical Industry in India and acknowledged our points. The Hon'ble Minister informed that he had already initiated action on many of the issues with other concerned Ministries.

MSME further redefined to support Manufacturers

The Hon'ble Finance Minister Mrs Nirmala Sitharaman had revised the definitions of MSME on 13 May 2020 to include investment and turnover, as discussed in the Executive Committee meeting. However, under this revised definition, even medium scale units covered investment only upto Rs. 20 crores and turnover upto Rs. 100 crores. As this was inadequate for setting up a pharma manufacturing unit or for growth of existing units, we requested Government to increase the turnover limits to provide better growth-friendly incentives to MSMEs. On 1st June 2020, Ministry of MSME issued a notification [GSR 1702] revising the definitions further to restrict it to manufacturing units only covering investments in Plant and Machinery or Equipment, as: (1) micro enterprise redefined as investment upto Rs 1 crore and turnover upto Rs 5 crores, (2) SSI investment upto Rs. 10 crores and turnover upto Rs 50 Crores and (3) medium enterprise with investment upto Rs. 50 crore rupees and turnover upto Rs 250 crores. Government also informed that exports will not be counted in turnover for any enterprise whether micro, small or medium.

Meeting with Ms Aparna, IAS, DOP Secretary

IDMA had a virtual interactive meeting on 3 October 2020 with Ms S Aparna, IAS, the new Secretary of Department of Pharmaceuticals. The Secretary was keen to first talk to IDMA and hence the meeting was organised in a very short time. National President was joined by Past Presidents, Secretary – General, various Committee Chairmen and over 30 EC Members in the meeting. We informed the Secretary about a few urgent and pending issues such as Track & Trace System, Fall Clause, FDCs, revision of Schedule M, GST, Pricing, Environmental issues, PLI Scheme etc. We thanked DOP for their initiative in launching the PLI Scheme. The Secretary appeared to have taken note of the developments and appreciated the dynamism of her predecessor Dr P D Vaghela. She promised her support in all matters and agreed to interact regularly with us in future too to address issues.

Felicitation of Dr. P.D. Vaghela, IAS

On 29th September 2020, all the Associations representing Pharmaceuticals and Medical Devices held a VC meeting with Dr. P.D. Vaghela, Secretary, DOP and felicitated him on his superannuation. We thanked him for his various initiatives in support of industry during COVID-19 pandemic, specially during the early days of lockdown period, and also his continued support during his tenure. Dr Vaghela later took charge as Chairman of TRAI.

Meeting under the Chairmanship of Hon'ble CIM Mr. Piyush Goyal with Chambers of Commerce & Industry Associations

Our National President attended the virtual meeting under the Chairmanship of Hon'ble CIM Mr. Piyush Goyal with Chambers of Commerce & Industry Associations hosted by DPIIT, Ministry of Commerce & Industry on 24 November. Hon'ble Shri Som Parkash, Minister of State, Ministry of Commerce & Industry and other officials were also present. We thanked the Government for reposing the faith in the Pharma Industry with launch of first PLI scheme of Rs 10,000/ Crore and now the second PLI scheme of Rs15,000/- Crores. We raised a few key issues and concerns requesting Government for protection of Investment/ Business security. We requested that MEIS scheme be extended to 31st March, 2021 and for all shipments of this year MEIS may please be given.

WEBINARS DURING THE YEAR:

1. Knowledge Series with OPPI, IPA & IDMA
2. IDMA GSB Webinars

   *IDMA GSB had organized various Webinars during 2020 on different topics. But the starting one which was indeed different was **"Resetting the entrepreneurial mindset for the new normal"** by Param Pujya Swami Gyanvatsalji on 30th May 2020.*

3. *Dr Mickey Mehta Wellness Webinar*

   "MIND IS MEDICINES" - a webinar by Dr Mickey Mehta, Global Leading Holistic Health Guru & Corporate Life Coach was organized on 6th June 2020.

4. ***IDMA Marketing Committee Webinar***

   *IDMA Marketing Committee jointly with NextPlan Consulting organized a Webinar on **"New Normal - Post COVID-19"** on 8th August 2020. The webinar was supported by AIOCD Pharmasofttech AWACS Pvt Ltd. There were over 450+ participants*

5. *IDMA – iMedrix Webinar on "Telemedicines Applications for Physician Engagement During #COVID Times"*

   *IDMA, in association with iMedrix, organized a Webinar on **"Telemedicines Applications for Physician Engagement During #COVID Times"** on 29th August 2020.*

6. ***IDMA Webinar on Disposal of Expired Medicines with SOCIAL TALKS***

   *As proposed by Department of Pharmaceuticals, IDMA celebrated Swatchhata Pakhwada Day on 10th September 2020 by organising a **Webinar on Disposal of Expired Medicines** jointly with Social Talks, New Delhi. Shri Atul Nasa, Head of Office/Controlling Authority/Licencing Authority/Deputy Drugs Controller, New Delhi & Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone, Mumbai were the Guests of Honour. Over 900 registrations were recorded and about 517+ participants were present in the Webinar.*

7. ***IDMA-Aptar Webinar on Ocular Drug Delivery***

   *IDMA and Aptar Pharma had jointly organised a Webinar on **"Ocular Drug Delivery; A Therapeutic Area with an Interesting Past and a Fascinating Future"** on 5th November 2020.*

8. ***IDMA & SOCIAL TALKS – 100 Most Impactful Corona Warrior Awards towards Honouring of Corona Warriors***

IDMA jointly with Social Talks, New Delhi organised the 100 Most Impactful Corona Warrior Awards on 10th November 2020 wherein 100 Corona Warriors whose hard work, kindness, support and excellent service to humankind during this Covid-19 Pandemic was recognized and honoured. From IDMA, Mr. Melvin Rodrigues & Mr. Ajay Kumar Singh along with me were honoured with a Certificate & Medal.

Dignitaries to grace the Executive Committee Meetings in 2020:

(1) Mr Pankaj Patel, Chairman, Cadila Healthcare Ltd (Zydus Group)

(2) Dr Amol Kulkarni, NCL, Pune

(3) Dr Deven Parmar, Chairman, Medical Committee

(4) Mr Premchand Godha, CMD, IPCA Laboratories Ltd

(5) Mr Arun Singhal, IAS, CEO, FSSAI

NEW APPOINTMENTS DURING THE YEAR :

1. ***Dr Harsh Vardhan, new Chairman of WHO Executive Board***
2. ***Dr P B N Prasad as Jt. Drugs Controller (India)***
3. ***Shri Arun Singhal, IAS*** *as the CEO of FSSAI*
4. ***Shri Rajesh Bhushan IAS*** *as Secretary, Department of Health and Family Welfare*
5. ***Dr Sunil Kumar*** *as Director General of Health Services (DGHS).*
6. ***Shri Satish Kumar Gupta, IRS*** *was reappointed as Member, Central Board of Direct Taxes (CBDT).*
7. ***Shri Hardik Shah,*** *a 2010 batch IAS officer, as the new Private Secretary to Prime Minister Shri Narendra Mody.*
8. ***Ms. S Aparna, IAS,*** *(Gujarat 1988 cadre) as Secretary, Department of Pharmaceuticals.*
9. ***Shri Vishal Chauhan, IAS*** *as* ***Joint Secretary,*** *Department of Health and Family Welfare.*
10. ***Shri Manohar Agnani, IAS Additional Secretary*** *will be in charge of CDSCO, Drugs and Cosmetics Act, FSSAI, Indian Pharmacopoeia Commission, COVID vaccination, all Procurement matters, etc among other things.*
11. ***Shri Alok Saxena, Jt Secretary*** *will be Chief Vigilance Officer, and also look after NACO, NGO, Parliament Matters etc among other responsibilities.*
12. ***Ms Preeti Pant, Jt Secretary*** *will be taking care of Family Welfare related matters.*

REMEMBRANCE OF STALWARTS

(1) Shri K D Vora, *Partner, Pure Drugs (India)*

(2) Shri J B Mody, *Chairman and Managing Director of M/s J B Chemicals and Pharmaceuticals Ltd (JBCPL)*

(3) ***Mr D D Chopra,*** *was a Senior IDMA Executive Committee Member for many years and was an expert on pricing & related matters*

(4) ***Dr R S Joshi*** *was the Executive Secretary of IDMA Gujarat State Board for over two decades and his contribution towards the initiatives & activities of IDMA-GSB was invaluable*

(5) ***Mr K C Kohli*** *was an Advisor to IDMA on Pricing related issues, DPCO & NPPA matters and assisted IDMA in preparing several representations to the Government on various issues*

(6) ***Shri Ram Vilas Paswan,*** *Union Minister of Consumer Affairs, Food and Public Distribution in the Prime Minister Narendra Modi led Government, who passed away on 8 October 2020.*

(7) ***Shri Subharthee Dey,*** *Whole Time Director at Dey's Medical Stores Ltd. He was a very active senior member of IDMA for more than 3 decades where he was elected the first Vice President (Eastern Region). The Pharmaceutical Industry in the Eastern Region grew immensely largely due to his efforts in guiding the West Bengal State Board in its initial years,*

(8) ***Shri B. Sethuraman,*** *Managing Director, Abilash Pharma Pvt Ltd. He was instrumental in founding the Federation of South Indian Pharmaceutical Manufacturers Association (FOSIPMA) and Confederation of Indian pharmaceutical Industry (CIPI) and was Chairman of FOSIPMA and Secretary General of CIPI for many years. He was also President of Pharmaceutical Manufacturers Association of Tamilnadu (PMA, Tamilnadu). He was actively involved in IDMA TNPKSB activities.*

All the Past Presidents expressed their appreciation of National President Mr Mahesh Doshi for his dynamism and active team work in guiding the Members and the Indian Pharma Industry during the ongoing lockdown period due to COVID-19. They also congratulated Mr Doshi for bringing IDMA into prominence again as the Voice of the Indian Pharma Industry. National President thanked the Past Presidents and all Members for their support and co-operation and informed that it has been a learning experience for him as how even Government officials can respond quickly to address and resolve issues in such emergencies.

The detailed report of various Expert Committees follows.

Wishing you all a Safe, Healthy, Fruitful, Profitable & Covid-19 free Financial Year 2021-22.

Daara B Patel
Secretary-General

59TH ANNUAL REPORT 2019-20

REPORT OF BULK DRUGS COMMITTEE 2019-20

China - Coronavirus aftermath – APIs and Intermediates - medicines supply positions

Following the outbreak of Coronavirus in China, Government of India was concerned about the impact on supply of APIs and Intermediates and availability of medicines. Government took up the matter as National Health Security measure and an urgent meeting was organised by NITI Aayog on 19 February 2020. The meeting was chaired by Mr Amitabh Kant, CEO, NITI Aayog. Mr C K Mishra, Secretary, Environment and other officials were also present. We emphasised that for 50% increase in capacity, pollution load certificate was required but no time limit was specified. There should be a time limit and if not given in that time, it should be deemed to be granted. Also 50% increase was too low for API Industry and the Industry should not be equated with other sectors.

Various other meetings were also held by DOP, DCG(I), CDSCO, Dept of Commerce etc on this urgent issue. Industry was reportedly confident about sufficient stock of medicines with retailers and hospitals. Stocks of APIs and intermediates were reported to last for 2 to 3 months. Regarding increasing availability of fermentation products such as Pen. G, Tetracycline, Erythromycin, Ceftriaxone Sodium, Amikacin Sulphate, Meropenem, Azithromycin etc., we informed that new fermentation units would require an investment of Rs.100 to 200 Crores and may take minimum 12 to 18 months' time. As requested by Government, we emailed a circular to all Members seeking urgent information on the stock in hand for APIs, intermediates and formulations.

5th API Task Force meeting

The 5th meeting of Task Force on APIs was held on 17 February 2020. Dr Chinmay Majmudar informed that the meeting was chaired by Hon MoS Shri M. L. Mandaviya. Dr P. D. Vaghela, Secretary and other officials from DOP were also present along with DCG(I) Dr. Somani, and officials representing other Departments. We made a presentation and replied to all the queries of the Hon. Minster and Secretary DOP and counter questions raised by Dr Sharath Pallerla, Director, Ministry of Environment. We emphasised that there was an urgent need to fast track EC and approvals that have been hindering the production and growth of API sector. National President informed that the Ministry of Environment had earlier issued a notification [S.O. 236 dated. 16 January 2020] allowing 50% increase in quantity of product mix.

Government plans for the future

Most of the raw materials for antibiotics, vitamins, hormones etc, whether as API, Intermediate or KSM are at present sourced only from China, which undermines our National Health Security.

Government has proposed plans to boost production of 53 APIs, which if properly implemented could go a long way in reviving our API industry. Mr Yogin Majmudar, Chairman, Bulk drugs Committee informed that Government had worked out two schemes:

(a) Promotion of Bulk Drug Parks for financing Common Infrastructure Facilities in 3 Bulk Drug Parks, with financial implication of Rs. 3,000 crore for next five years.

(b) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs in the country with financial implications of Rs 6,940 crore for next eight years.

In his VC meeting with Dr Eswara Reddy, Jt DCG(I), he had again cautioned that existing API units required immediate support to ease Environment compliances and boost production. Setting up bulk drug parks was a long term measure. As a short term measure, Government must incentivise SMEs and certain large companies which were earlier API producers but stopped producing on account of Chinese companies dumping at very low cost. We must not miss the opportunity provided by COVID-19, which was a wake-up call for India and we must adopt short, medium and long term strategy to make India self-sufficient in KSMs, intermediates and APIs. It appeared that Government had set some strict policy measures such as allowing only one manufacturer to produce one drug. Members discussed that this would create monopolies and would be counterproductive. As it was expected that Dr Reddy might organise a meeting immediately, it was decided that a separate meeting of Bulk Drugs Committee be held at 4.00 p.m. immediately after the conclusion of the EC meeting to work on strategies to be proposed to Government to support brownfield manufacturers

Mr Majmudar informed that the Ministry of Environment & Forests had uploaded a draft Environment Impact Assessment Notification, 2020 (EIA notification) on their website on 12 March 2020 requesting for comments to be submitted within 60 days. He had requested the experts Mr Kaushik Samantha of Lupin Ltd and Mr Harish Verma of Cipla who had represented the industry at the Expert Committee meetings on this matter to prepare our comments and suggestions.

Proposed 15% COVID-19 tax on chemical imports from China

Members discussed that Chemexcil had reportedly proposed to Government to impose 15% COVID-19 tax on all chemical imports. National President clarified that the proposal appears to have been made by the Department of Chemicals and Petrochemicals on specific Chapters 28, 29 and other related Chapters which has been accepted by Chemexcil. Members discussed that this will need to be countered as prices of many chemicals were already very high and it could hike the prices further. It would also be counterproductive and lead to non-availability of many chemicals. After discussion National President proposed that we make a submission to DCPC not to impose the COVID-19 tax broadly chapter-wise and if required, it could be considered on certain selected Chemicals only.

DOP VC meeting with stakeholders to discuss the schemes related to Bulk Drugs and Medical Devices

A Video Conference was held by DOP with Industry Associations on 26 May to discuss schemes related to Bulk Drugs and Medical devices. Along with him, Dr Dinesh Patel, Mr Yogin Majmudar, Mr Bharat Shah, Mr Daara Patel and Mr Ashok Madan represented IDMA at the meeting. Dr P. D. Vaghela Secretary, DOP chaired the meeting. Presentation was made by Mr Navneet Rinwa, Jt Secretary, DOP and Dr Eswara Reddy, Jt DC(I). National President requested Mr Yogin Majmudar, Chairman, Bulk Drug Committee to brief Members. Mr Majmudar informed that we emphasised that for fermentation based products PLI scheme will not be feasible. Also financial support should be for long term and not short term incentives. However the officials insisted that investment and quantity are interlinked, and investment is a key parameter for Government. The need is for latest technology and not obsolete technology. Government audits require investment figures and not only production figures to consider budget utilisation.

Notice period for submission of comments on draft EIA notification extended

The Ministry of Environment & Forests had published a draft Environment Impact Assessment Notification, 2020 (EIA notification) in the official gazette on 11th April 2020 requesting for comments to be submitted within 60 days. The Ministry has extended the notice period up to 30 June, 2020. We have requested our expert Mr Kaushik Samantha of Lupin Ltd to prepare our comments and suggestions.

PLI Scheme notified for APIs, KSMs

DOP notified PLI Scheme for promotion of domestic manufacturing of KSMs and APIs on 2 June 2020. He requested Mr Yogin Majmudar, Chairman, Bulk Drugs Committee to brief Members. Mr Majmudar informed that following our suggestions, the Scheme now recognised brownfield units too. A Nodal agency would implement the Scheme. An Empowered Committee would consider and approve applications forwarded by the Project Management Agency after scrutiny. Members deliberated on the proposals. It was discussed that PLI scheme promoted manufacturing of KSMs and preference would begiven to encourage backward integration by manufacturers of the concerned API and not “increase” capacity of what was already being manufactured. The main objective would be to manufacture the KSMs that are being imported at present.

IDMA submission on draft EIA Notification 2020

We have submitted our comments and suggestions on the draft Environment Impact Assessment 2020 notification on 23 June 2020 to DOP Secretary and MoEF&CC Secretary. We have also highlighted our reservations. The EIA Notification persists with the cumbersome procedures and highly technical guidelines. We have submitted that most MSMEs, who comprise bulk of API

manufacturers in the country, do not understand the fine print of the 83 pages document. Simplified guidelines are necessary which eliminate various approvals as currently required to manufacture the API, and which still continue to be part of the new document.

Special Session on PLI Scheme by Dr Amol Kulkarni, NCL, Pune

Dr Amol Kulkarni, NCL, Pune informed that PLI Scheme for APIs, Intermediates and KSMs is an excellent scheme. He was a part of the scientific group that prepared this scheme. According to him, such a scheme was very late in being introduced by at least a couple of decades. The scheme is not for everybody as the focus is on backward integration and required expertise in pharmaceutical production technologies. India is heavily dependent on imports of KSMs and we need to change this dependence. China has world sized plants and hence are able to make and supply at cost effective volumes.

Ideally, the manufacturer should be prepared to scale up production capacity for global requirements. This will make the scheme really viable and meaningful, as the economy of scale will ensure a good price for the product. The focus should be on innovative technologies and business models such as efficient processes of synthesis, continuous manufacturing technologies etc. He suggested that world sized plants require huge investments which can be achieved by joining hands with other manufacturers for the common interest of getting assured regular supply of the KSM or intermediate in case of API manufacturers or the API, in case of formulators.

He informed that NCL has developed miniature glass-coated flow reactors with high performance and better compatibility occupying lesser space. Such reactors can be used to handle intermediates and other chemicals in manufacturing process and can handle extreme temperatures at affordable prices.

Dr Kulkarni also interacted with Members and responded to queries. He informed that the continuous flow reactors technology that NCL has developed required no solvents and would be a cost saver for taking up manufacturing of any chemical in the PLI scheme. He said that the number of manufacturers for each of the APIs or KSMs etc was limited to avoid internal competition. Exports can be considered for offsetting cost of production for domestic requirements. He concluded that NCL Pune was eager and willing to join hands with IDMA in taking up production of any chemical under the PLI scheme and also any other API or intermediate that any Member wishes to pursue for their growth.National President thanked Dr Kulkarni for his informed analysis of the PLI scheme.

PLI Scheme for APIs and Bulk Drug Parks

DOP had issued notifications of PLI Scheme for promotion of domestic manufacturing of APIs and Scheme for promotion of Bulk Drug Parks on 21 July. The Guidelines were later released on 27 July at a Press Conference by Shri D V Sadananda Gowda, Hon'ble Minister of Chemicals and Fertilisers. He requested Mr Y R Majmudar, Chairman, Bulk Drugs Committee to brief Members. Mr Majmudar informed that the Guidelines were very complex and there were very few takeaways. The proposed Domestic Value Addition should be at least 90% in case of fermentation

based product and at least 70% in case of chemical synthesis based product, which would mean allowing only 10% and 30% import content respectively. The conditions specified that Net Worth of the Applicant should not be less than 30% of the total proposed investment, which effectively eliminated SSIs. Members discussed that DOP had been cautioned about the need for Business Security for potential applicants. It was almost certain that once production began, China would begin exporting these APIs and KSMs to India at a much lower price than economically viable to the Indian manufacturers. Certain measures such as Anti-Dumping, CVDs and SDs would need to be invoked to counter the threat whenever it is required.

DGTR VC meeting with Industry

Mr Yogin Majmudar, Chairman, Bulk Drugs Committee informed that the DGTR held a VC meeting on 17 August with the Pharma Industry on anti-dumping duties levied on import of bulk drugs from China. The meeting was chaired by Dr. Rajiv Arora, Addl. DGTR. Mr. Shyamal Misra, JS (Commerce) and Dr. KV Nagi Reddy, Director (Commerce) were also present in the meeting. Industry was also represented by Pharmexcil, IPA, BDMA etc. Many issues were discussed and we raised the concern about Chinese companies resorting to predatory pricing to block the PLI scheme from succeeding. As requested by Addl. DGTR, we made a representation on 19 August on the issue of predatory pricing from China since 1990s highlighting that, once the PLI Scheme of DOP was implemented, China might again resort to predatory pricing and requested that measures be adopted to counter the situation.

DOP PLI Scheme – PHDCCI Webinar

PHD Chamber of Commerce and Industry had organised a webinar on 25 August as part of their 3D Virtual Health & Wellness Expo & Conferences from 21st August to 25th August 2020. The Webinar was on “Brainstorming the strategies for positioning India as a HUB for API - Atma Nirbhar Bharat”. Dr Eswara Reddy, Joint DCG(I) responded to all issues and concerns of the industry represented by IDMA, IPA and BDMA with Mr B R Sikri leading the way. Dr Reddy assured that they were working on a second list of APIs that would also include excipients. He requested the associations to urgently submit representations on the amendments required in the PLI scheme. Mr Majmudar informed that IDMA and BDMA were jointly working on a representation highlighting about 11 points regarding certain concerns and shortfalls to be covered in the PLI scheme and it would be submitted to the Jt DCG(I) very shortly. He informed that in our submission we are requesting that since new units would take at least 2 years to begin production, brownfield units may also be considered for the new scheme as their idle capacities can be used to produce the products. We have also pointed out, among other things, that the Cost based approach requires estimation of costs over an 8 year period and if an applicant estimates higher cost or lower cost, the firm will lose huge marks or lose huge subsidy. Similarly 30% Net Worth condition was stringent and effectively rules out some of the MSMEs who otherwise would be technically competent to produce the product.

IDMA-BDMA joint Submission on issues in PLI Scheme Guidelines

Mr Yogin Majmudar, Chairman, Bulk Drugs Committee informed that, as proposed at the last EC meeting, IDMA-BDMA jointly made a submission to Dr Eswara Reddy, Jt DCG(I) on 31 August highlighting certain urgent and important corrections that were needed in the PLI Guidelines. We have requested that, along with Greenfield category, brownfield category units must also be considered to avail this new scheme which will give immediate results as idle capacities can be used to produce the products. Also Cost based approach requires estimation of costs over an 8 year period. If a firm estimates higher cost or lower cost, the firm will lose huge marks or lose huge subsidy. This pressure on applicant leads to unnecessary errors to get eligibility. We have requested that, as GST is an auditable transparent record, it can be used for sales declaration and computation of incentives. There are certain anomalies in capacity commitments and returns which need to be rectified for better results. We have also emphasised that for quick changeover of products, we need consent from Pollution Control Boards for "API Intermediates" instead of individual product-wise apprval, so that an API manufacturing unit can change the product mix whenever required without increasing the load of pollution.

Environmental approvals as 'Bulk Drugs and Intermediates'

Mr Majmudar informed that there was one positive development towards Environment approvals of bulk Drugs. Maharashtra PCB had earnestly taken up our proposal of granting license to the category "Bulk Drugs" instead of each bulk drug by name. An Expert Committee has been set up with Members representing ICT, NEERI, NCL MPCB, etc. Dr Chinmay Majmudar is representing the Bulk Drug Industry in this Committee. He requested Dr Viranchi Shah to take up the issue with GPCB so that if Maharashtra or Gujarat approve this process, all other States will follow suit. Dr Viranchi Shah informed that they had already represented to GPCB and others in August 2020that EIA Notification 2006 had listed "Bulk Drugs" under 5(f) as a single entity. We have requested that all Consents for these products be given as "Bulk Drugs & Intermediates". Also a notification was issued earlier this year granting "B2" category to Bulk Drugs until 30 September 2020. We have thus requested that the categorisation "B2" be continued till 31 March 2021 and the category be listed correctly as "Bulk Drug & Intermediates".

API PLI Scheme - Guidelines further revised on 29 October 2020

DOP had released further revised Guidelines for the API PLI Scheme on 29 October 2020. Mr Majmudar informed that DOP amended certain provisions such as:

a) Replacement of the criteria of 'minimum threshold' investment with 'committed' investment by the selected applicant to encourage efficient use of productive capital as the amount of investment required to achieve a particular level of production depends upon choice of technology and it also varies from product to product.

b) Export is now allowed, though the wordings in the Guidelines only imply it, as the provision which restricted sales only to domestic market for the purpose of eligibility of receiving incentives has been deleted.

c) Change in the minimum annual production capacity for 10 products viz Tetracycline, Neomycin, Para Amino Phenol (PAP), Meropenem, Artesunate, Losartan, Telmisartan, Acyclovir, Ciprofloxacin and Aspirin. Minimum annual production capacity is part of eligibility criteria under the scheme.

d) The last date for receiving applications under the scheme is now extended by a week to 30.11.2020.

National President informed that DOP had also organised a VC meeting on 29 Oct 2020 in which he had participated along with Mr Majmudar and Mr B R Sikri and others. Mr Majmudar informed that they had again raised the issue about allowing brownfield units also to participate to encourage small and medium enterprises. Also it would speed up production of these APIs as the gestation period required for new units would be largely reduced. Mr Sikri informed that he had been scrutinising the revised Guidelines and many provisions would still need to be sorted out to encourage industry. He proposed that IDMA and BDMA discuss the issues and submit a joint representation to Dr Eswara Reddy, Jt DCG(I) and DOP.

Government approves further PLI scheme of Rs 15000 crores - Meetings on PLI scheme - Joint Submission by IDMA, BDMAI, FOPE and FICCI

National President informed that on 11 November 2020, Union Cabinet approved a further grant of Rs 15000 crores under the PLI Scheme for various categories of drugs. Along with Intermediates, APIs, KSMs as a category, Biopharmaceuticals, complex generics, drugs going off patent, Repurposed drugs, Orphan drugs; Special empty capsules; complex Excipients, Auto Immune Drugs, anti-cancer, anti-diabetic, drugs not manufactured or not approved in India etc have also been listed in the Scheme. A meeting was organised by DOP on 17 November to discuss the matter with industry. He attended the meeting along with Mr Yogin Majmudar, Chairman, Bulk Drugs Committee and Mr Ashok Madan. He requested Mr Majmudar and Mr B R Sikri to brief Members. They informed that PLI Scheme II was more favourable to industry. Also DOP Secretary Ms S Aparna, IAS was willing to listen to industry suggestions and concerns. Replying to our query, the Secretary informed that the new Scheme, though not yet formally notified, covers formulations also along with APIs. After our repeated requests, the investment limit was lowered to Rs 50 crores and we have further requested to lower this down to Rs 25 crores to enable SSI manufacturers to participate. Also the investment is to be made over a period of 4 to 5 years. The Government may set the limit in three categories: Rs 100 Crore for Rs 1000 crore and above turnover, Rs 50 crore for Rs 500 crore to Rs 1000 crore and Rs 25 crore for all others. Government is very particular that the focus is on new units as this will increase employment opportunities and boost economy. We have requested to allow existing units also to be considered with new plant and machinery. We have also requested that investment should include cost of acquiring land, as it is a major factor. Also expenses incurred in conducting Clinical Trials, Patent filing and Registration etc should also be considered. Members discussed that only an outline has been provided so far and the provisions of the PLI scheme will be clearer once the Guidelines are released.

Mr Majmudar informed that following the meeting on 17 November, IDMA, BDMA, FOPE and FICCI made a joint representation on 19 November again raising these and other points that the Scheme should be as simple as possible without any ambiguities and cumbersome procedural requirements with focus on technology innovation and value creation and not on net worth, investment and selling price. There should be no reservation for any specific Sector. And for the PLI scheme to succeed, major relaxations must be given to the Industry by MoEF&CC from the present outdated guidelines. Mr Sikri informed the previous PLI scheme was not successful as there were too many limitations and conditions that discouraged industry from participating. Government at present was not willing to guarantee business security. Discussions between Government and industry will continue regularly.

MoEFCC notification extending validity of EC

The Ministry of Environment (MoEFCC) has issued a notification dated 27 November 2020 extending validity of prior Environmental Clearances till 31 March, 2021 or six months from the date of expiry of validity, whichever is later.

VC meeting on Environment Rules

Ms. S Aparna, Secretary, DOP and Mr. Rameshwar Prasad Gupta, Secretary, MoEFCC jointly called a meeting on Environment Rules on 10 December 2020. Mr. Yogin Majmudar, Chairman, Bulk Drugs Committee had represented IDMA at the meeting. Mr. Majmudar informed that MoEFCC was represented by a team of officials including Mr. Sharath Pallerlla, Scientist F and Mr. Dinabandhu Gouda, Addl. Director, CPCB. It was a very successful meeting due mainly to the efforts of Ms. Aparna, Secretary, DOP and the positive responses of Mr. Gupta, Secretary, MoEFCC and they addressed and resolved most of our issues. We will need to wait for the legislation from MoEFCC to get confirmation on the relaxations and amendments.

Subsequently, in January and March ’21 by two separate communications, MoEF&CC has agreed to issue EC as single category “API & Intermediates”, and also allow changes in product mix / quantity / plant & machinery without prior EC, as long as there no increase in Pollution Load. IDMA + BDMA representations are made to MoEF&CC and Secretary, DoP to also provide similar flexibilities to State level permissions of CTE & CTO.

Meeting on fixation of Standards for Pharma Industry

Mr. Majmudar informed that, on 9 December 2020, Mr. Navdeep Rinwa, Joint Secretary, DOP had held an Inter-departmental meeting with officials of Ministry of Environment along with technical experts from IDMA and BDMA on fixation of Standards for Pharma Industry. Mr Kaushik Samanta from Lupin and Mr. Harish Verma from Piramal along with Mr Majmudar representing IDMA. BDMA was represented by Mr. R K Agarwal. Mr. Jigmet Takpa, Joint Secretary, MoEFCC, Mr. Sundeep – Scientist F and Mr. Dinabandhu Gouda, Additional Director, CPCB were also present. MoEFCC had notified very stringent draft Rules on AMR. The draft Rules was extended

to cover almost all therapeutic categories of drugs and formulations and covered all manufacturing units involved in APIs and formulations. It was almost impossible to comply or implement. After our explaining the issues in detail, the officials have agreed to simplify the draft Rules and limit it to scrutinizing COD, BOD levels in effluents. Subsequently, MoEF&CC have agreed to remove AMR limits from the draft Rules.

Positive response to API PLI Scheme I

Ministry of Chemicals and Fertilizers issued a Press Release on 1 December 2020 stating that they received 215 applications from 83 pharma manufacturers and 28 applications from 23 medical device manufacturers under PLI schemes. The closing date of applications was 30 November 2020. IFCI Ltd. is the Project Management Agency (PMA) for implementation of both the schemes. The appraisal process of the applications would commence from 1 December 2020 and a maximum of 136 applications under the PLI scheme for bulk drugs and a maximum of 28 applications for medical devices would be approved. The time duration for giving approval to the applicants was 90 days under the PLI scheme for bulk drugs and 60 days for medical devices.

Government had approved another detailed PLI scheme for Pharmaceutical industry in November 2020 covering a wider range of drugs and formulations that would be formalized after industry concerns were addressed. DOP issued an Office Memorandum dated 9 December 2020 informing about forming of Technical Committee for this PLI scheme with Dr. S Eswara Reddy, Jt. DC(I) as Chairman and Members Dr. Amol Kulkarni, NCL Pune, Prof. Arvind Bansal, NIPER, Mohali, Mr. Satish Khanna, Chairman, Fullife Healthcare and Mr. Srinivas Lanka, Hon Sr. Adviser, Pharmexcil.

Mr Yogin Majmudar and Mr B R Sikri had attended the meeting with DOP along with National President to discuss the second PLI scheme. They informed that the discussions were still in progress in trying to convince Government to include existing manufacturers. They have also proposed to Government to lower the investment limits to Rs. 25 crores for SSI units for formulations and Rs. 15 crores for API units. The Ministry of Chemicals and Fertilizers was also working on a similar PLI scheme for chemicals. Mr Sikri proposed that we may need to send a representation to the Expert Committee requesting for lowering investment limit from Rs. 100 crores to Rs. 25 Cores/ Rs. 15 Crores as discussed in the second PLI scheme.

National President informed that Mr C V Venkataraman, Vice-Chairman, Pricing Committee also has a few issues on the PLI Scheme. Mr Venkataraman informed that Lupin has applied for participation the PLI Scheme, but certain provisions and procedures are turning out to be regressive. We need to seek clarification from DOP the reason for IFCI seeking CIBIL report to process the application. CIBIL reports are required by banks for disbursing loans whereas the PLI scheme is to provide incentives. As incentives would be disbursed only after verifying actual production under the PLI scheme, there is no need for CIBIL reports. Also list of all quantifiable as well as non-quantifiable cases against and by the companies are required to be informed in

writing to them. When due to COVID many companies' offices are closed, IFCI is insisting on original signed documents and are not willing to accept Digital signature. Mr Majmudar requested that the points may be forwarded to him to take up during the next meeting with DOP on PLI scheme.

REPORT OF EMPLOYEE RELATIONS DEVELOPMENT COMMITTEE

FMRAI advising MRs not to 'Work from Home'

During this lockdown, travelling was restricted and employees were required to maintain social distancing by working from home. Medical Representatives (MSRs) were however refusing to work from home on the advice of their union FMRAI. This was affecting the marketing and promotion activities of companies. We submitted a representation dated 30 April 2020 to the Hon'ble Minister of Home Affairs Shri Amit Shah highlighting the non-cooperation of the MSRs. Disregarding the specific instructions of our Hon'ble Prime Minister and Ministry of Home Affairs, some unrecognized Trade Unions, including FMRAI and other affiliated Unions to FMRAI were advising their members not to co-operate with the Companies and also not to participate in any digital meeting and also not to complete any assignments as per facility of 'Work from Home' given to them. Also, FMRAI vide their letter dated 20th April 2020 addressed a letter to Ministry of Home Affairs sought suspension of work for PSR/Medical Representatives. They mentioned that lockdown measures are being followed but missed an important responsibility of 'Working from Home' as per directives of the Ministry. They instructed their members not to follow the lawful Orders of carrying out 'Work from Home'. We requested the Hon'ble Minister to direct the said Unions not to instigate or prevent the PSR/Medical Representatives to disobey lawful orders of 'Work from Home' in this time of dire need.

Draft Code on Wages (Central) Rules, 2020

The draft Code on Wages (Central) Rules, 2020 [G.S.R. 432] was released on 7 July 2020. The Code subsumes four labour laws -- Minimum Wages Act, Payment of Wages Act, Payment of Bonus Act and Equal Remuneration Act. There are 12 definitions of wages in different labour laws leading to litigation besides difficulty in implementation. The definition has been simplified in the Code. The Code also universalises the provision of minimum wages and timely payment of wages to all employees irrespective of the sector and wage ceiling. At present, the provisions of both Minimum Wages Act and Payment of Wages Act apply on workers below a particular wage ceiling working in Scheduled Employments only. The Code addressed the problems relating to delay in payment of wages and provides for eight hours working day.

Draft OSH Rules 2020

The Ministry of Labour and Employment released a draft Notification [G.S.R. 729 (E) dated 19th November, 2020] on the Occupational Safety, Health and Working Conditions (Central) Rules, 2020.

REPORT OF EXCISE AND TAXATION COMMITTEE

Direct Taxes: Practical difficulties from certain provisions of Budget 2020 – IDMA Submission

Mr B G Barve, Chairman, Excise & Taxation Committee informed that certain issues had cropped up by CBDT keeping due date of various audit reports by one month 30 September prior to due date of filing Return of Income (31 October). Due to amendments in Budget 2020-21, 18 such audit reports would be required to be filed before the due date leading to practical difficulties. Another major issue was TCS on B2B sale of goods. Budget proposed TCS of 0.1% on B2B sale of goods, with no exception provided for export sales. The rate increases to 1% if the buyer does not have PAN and if the buyer does not have PAN or Aadhaar card, the rate of TCS further increases to 5%. We made a submission on 17 February 2020 highlighting these issues and requested for suitable amendments by specifically excluding exports from ambit of TCS in the Finance Bill where NR buyer has no taxable income in India.

Modes of payment specified for Sec 269SU under IT IDMA Representation

The Chairman Mr Barve informed that CBDT had issued a notification G.S.R. 960(E) and a Circular No.32/2019 both dated 30th December 2019 wherein it was provided that every person having a business turnover of more than Rs.50 Crores would need to mandatorily provide facility for accepting payment through Debit Card powered by RUPay, UPI (BHIM UPI) and UPI Quick Response (QR) code. Facilities were also required to set up by the concerned entity before January 31, 2020 failing which penalty of Rs. 5000/- per day would be levied on them. We made a submission to CBDT on 29 January 2020 that as the Indian Pharmaceutical Industry worked only on B2B business model and all the payments were either on electronic platform or through Bank mode only, these modes of payment were not applicable or feasible and sought clarity on non applicability of this directive on B2B businesses.

China Coronavirus included in *Force Majeure* clause in Government Procurement

National President informed that the Department of Expenditure, Ministry of Finance has issued an OM on 19 Feb 2020 including the China Coronavirus outbreak under the *Force Majeure* clause in the Manual of Procurement 2017 to be treated as Natural Calamity.

Lockdown impact on Statutory Compliances and Regulatory requirements.

Mr B G Barve, Chairman, Excise and Taxation Committee informed that due to the lockdown, there was severe impact on statutory compliances and various regulatory requirements. Finance Minister announced extension of filing Income Tax returns and GST to 30 June 2020. We made a submission to Provident Fund Commissioner requesting to extend the timeline for filing Provident Fund Payments and Returns from 15 April 2020 to 30 June 2020 in line with extensions provided by Central Government for compliances of Direct and Indirect Taxes which has been accepted.

He explained the relaxations in Compliances of various Regulatory provisions as below:

- **Donation to PM CARES Fund:** Government has set up a new fund called the 'Prime Minister's Citizen Assistance and Relief in Emergency Situations Fund' (PM CARES Fund) to provide relief to people affected by the Covid-19 outbreak. An individual can claim 100 per cent deduction for donation made to PM CARES Fund, under Section 80G of the Income Tax Act, 1961 (Act). Ordinarily, Section 80G restricts the amount of donation qualifying for deduction to 10 per cent of the gross total income. Government has relaxed this limit if the donation is made to PM CARES Fund. Accordingly, one can claim a 100 per cent deduction for the amount contributed to this fund. Further, any donation made up till June 30, 2020, can be claimed as a deduction for FY 2019-20.
- **Extension of due dates:** The due date to file a belated return and a revised return for Financial Year (FY) 2018-19 has been extended from March 31, 2020 to June 30, 2020. Accordingly, an individual taxpayer who has not filed his income tax return for FY 2018-19, or who wishes to revise a tax return that has already been filed, can now file or revise the return on or before June 30, 2020.
- **Filing of e-TDS returns**: Further, the due dates for furnishing returns and filing statements by employer falling within the period March 20, 2020 and June 29, 2020, has now been extended to June 30, 2020. Hence, the due date for filing of e-TDS returns for the fourth quarter, which fall within this period, also stands extended, which could delay issue of Form 16/12BA for FY2019-20.
- **Due date for linking PAN-Aadhaar extended:** The deadline for linking PAN with Aadhaar was March 31, 2020, failing which the PAN number would have become inoperative. Due to the Covid-19 situation, this deadline has been extended until June 30, 2020.
- **Tax-saving investments:** On account of the lockdown in most parts of India during March 2020, it was difficult for individuals to make investments to claim tax deduction before 31st March. Hence, the Government extended this deadline of March 31 till June 30, 2020 for FY 2019-20. Care will need to be taken to ensure that a deduction for this investment is not claimed in FY 2020-2021 as well.
- **Vivad se Vishwas Act:** Government had recently introduced the Vivad se Vishwas Act, 2020, a dispute settlement mechanism with the objective of reducing long-pending litigation. This scheme provides complete protection from interest, penalty and prosecution, if 100 per cent of the disputed tax was paid on or before March 31, 2020. Further, if paid after March 31, 2020, but on or before June 30, 2020, 110 per cent of the disputed tax was to be payable. Under the tax relief measures due to Covid-19, the additional 10 per cent amount is not required to be paid if the amount is paid by June 30, 2020.
- **GST filings**: In March 2020, Union Finance Minister Smt Nirmala Sitharaman had announced several relief measures to cater to the taxpayers affected by India's initial 21-day lockdown. A tax ordinance was passed on 31 March 2020 to give an immediate effect to these changes. On 3rd April 2020, CBIC issued new CGST notifications for the changes. Additionally, a

detailed circular was issued to clarify any anomalies surrounding these notifications. In addition to the Finance Minister's announcements, a new set of notifications were also released for e-way bills and adjustment of the provisional ITC.

- **e-way bills**: The validity of the e-way bills was extended to 30th April 2020, where its validity period expires between the 20th of March 2020 and the 15th of April 2020.
- **Composition taxpayers**: The due date for submission of Form CMP-08 by the composition dealers for the January-March 2020 quarter was extended to 7th July 2020. Also, the return in Form GSTR-4 for the FY 2019-20 was extended till 15th July 2020 from 30th April 2020. All the composition taxpayers were required to file form CMP-02 for the FY 2020-21 to once again opt into the scheme. The requirement has been extended from 31st March 2020 to 30th June 2020. Accordingly, the form ITC-03 can now be filed by 31st July 2020.
- **GSTR-3B**: GSTR-3B due dates were shifted to June 2020 for all the return periods from February to April 2020. Although the due dates have not been extended, a late fee waiver provides a further time limit for the businesses. Also, the filing can now be in a staggered manner based on the annual turnover recorded in the previous financial year, irrespective of the state/UT in which the taxpayer is registered. Businesses with a turnover of more than Rs. 5 crore can file GSTR-3B for February, March and April 2020 before 24th June 2020 to avoid a late fee. They will not be charged any interest for the first fifteen days from the due date, irrespective of the payment. After that, a reduced interest rate at 9% per annum would be levied on the delayed GST payment where the GSTR-3B is filed before the newly specified due date.

Mr Barve informed that a consolidated Advisory on revisions in Tax filing/Returns dates would be circulated to all Members.

Relief packages announced by Minister of Finance

National President informed that starting from 13 May over the next 5 days, Mrs Nirmala Sitharaman, Hon'ble Minister of Finance announced measures for relief and credit support related to businesses, especially MSMEs to support Indian economy's fight against COVID-19. This support included:

- New definition of MSME and other measures for MSME along with raising the Investment limit which would also allow a large number of companies who had outgrown the limit to benefit. An additional criterion of turnover was also introduced and the distinction between manufacturing and service sectors eliminated. Revised definition would be (Micro - investment less than Rs. 1 cr and Turnover less than Rs. 5 cr; Small – investment < Rs. 10 cr and Turnover < Rs. 50 cr and Medium - investment < Rs. 20 cr and Turnover < Rs. 100 crore)
- Rs. 3 lakh crore Emergency Working Capital Facility for Businesses, including MSMEs
- Rs. 20,000 crore Subordinate Debt for Stressed MSMEs
- Rs. 90,000 crore Liquidity Injection for DISCOMs

- Rs. 50,000 crore equity infusion through MSME Fund of Funds
- No Global tenders for Government tenders of upto Rs. 200 crore
- e-market linkage for MSMEs promoted to act as a replacement for trade fairs and exhibitions.
- MSME receivables from Government and CPSEs to be released in 45 days
- Extending the Employees Provident Fund support for business and organised workers for another 3 months for salary months of June, July and August 2020
- EPF contribution to be reduced for employers and employees for 3 months to 10% from 12% for all establishments covered by EPFO for next 3 months
- Tax relief to business as pending income tax refunds to charitable trusts and non-corporate businesses and professions to be issued immediately
- Reduction in rates of TDS and TCS by 25% for the remaining period of FY 20-21
- Due dates for various tax related compliances extended
- The date for making payment without additional amount under the "Vivad Se Vishwas" scheme to be extended to 31 December, 2020.

Members discussed that there was a need to inform Government to further redefine MSME based only on turnover as today, for manufacturers interested in upgrading to international standards WHOGMP, USFDA etc, investment required was more than Rs. 10 crores for SSI or Rs. 20 crores for medium scale units. National President informed that this matter would be taken with Shri Piyush Goyal, Minister of Commerce & Industry at the proposed VC meeting on 31 May.

IT and GST matters date Extensions

Mr B G Barve, Chairman, Excise & Taxation informed that he was preparing a note on all circulars, notifications etc that were issued extending timelines and deadlines for Filings, Returns etc during COVID-19 pandemic and would be forwarding to the Secretariat for publishing in IDMA Bulletin.

GST and Tax updates

Mr B G Barve, Chairman, Excise and Taxation Committee informed that he had compiled the list of amendments and revisions including extending of timelines and deadlines made to GST, Income tax and other direct and indirect taxes from March 2020 when lockdown began till end May. This was already published in IDMA Bulletin for information of Members. Government further extended the lockdown and the revisions continue to be announced almost daily. He informed that another such list of revisions was being prepared.

Submissions on Hand Sanitisers at 12% GST

Mr B G Barve, Chairman, Excise & Taxation Committee informed that the Association had

made a detailed submission on 8 July 2020 to CBIC, GST Council, and DCG(I) seeking to retain GST at 12% under HSN code 3004 on Alcohol Based Hand Sanitisers (ABHS) as an antiseptic product. We were informed that the Directorate General of GST Intelligence (DGGI) had raised an issue about charging GST at 18% based on World Customs Organisation HS classification under 3808. A special virtual meeting was held on 17 July and it was decided to make a detailed submission to DGGI that pharma industry has been manufacturing ABHS as a drug/medicament with State FDA licence and following WHO specifications. Such disinfectants and antiseptics are covered in NLEM and price controlled by NPPA as drugs which attract 12% GST. Mr Jayaseelan, Chairman, TNPKSB informed that the confusion arose as some breweries were manufacturing Hand Sanitisers and selling under 18% GST. The Ministry of Health issued a Gazette notification [GSR 2451 dated 27 July 2020] notifying that 'Hand Sanitiser as a drug' no longer required a Drug Licence for stocking or sale. This confirmed our stand that Hand Sanitiser is a drug and hence GST applicable will be 12% and not 18% GST. The matter was now settled and Pharma Industry will continue providing Hand Sanitisers under 12% GST.

New Format/Schema for e-Invoices

Mr Barve informed that CBIC had notified [vide G.S.R. 481 dated 30 July 2020] that a registered person whose aggregate turnover in a financial year exceeded Rs. 500 crores would need to prepare e-Invoice from 1st October 2020. CBIC had also substituted a new Format/Schema for e-Invoice through FORM GST INV-01 vide CBIC Notification No. 60/2020 - Central tax dated 30th July 2020. We had analysed Invoice Schema to be implemented with our present Invoice pattern and observed that we need to include the following aspects in all types of Invoices with immediate effect:

1. Invoice Reference Number
2. Document Type to be INV/CRN/DBN instead of Regular
3. Supplier Place
4. Place of Supply (State Code)
5. Recipient Place
6. Is Service - Y / N

An Advisory is being published in IDMA Bulletin dated 7 August 2020 along with the notifications for information and necessary action of Members.

Developments and Updates in Direct and Indirect Taxes

National President informed that the Prime Minister had launched a scheme of 'Transparent Taxation - Honouring the Honest' on 13 August 2020 and invited Mr B G Barve, Chairman, Excise and Taxation Committee to brief Members about this and other developments related to Direct and Indirect Taxes. Mr Barve informed that there were many developments in Direct and Indirect Taxes, some of which he discussed as below:

(a) 'Transparent Taxation - Honouring the Honest'

As informed, Prime Minister Narendra Modi launched a platform for "Transparent Taxation - Honouring the Honest" with an aim to make the Tax system transparent, seamless and faceless. The key points were:

- Faceless appeal will be applicable from 25 September 2020 to all taxpayers across the country.
- Taxpayers Charter is a significant step where the taxpayer is now assured of fair, courteous and rational behaviour.
- There will be no physical interface between taxpayers and I-T Dept.
- Scrutiny, notice, and survey are currently handled by the IT officer in the same city. But now, it will be handled by technology and scrutiny will be randomised.
- The computer will randomly decide who gets to handle tax cases. For example, a Mumbai officer may survey tax related cases of someone in Guwahati.
- This system will eliminate the need of building relationships with taxpayer and tax offices.
- More transparency in official communication through the newly introduced Document Identification Number (DIN) wherein every communication of the Department would carry a computer generated unique DIN.
- Similarly, to increase the ease of compliance for taxpayers, the I-T Department has moved forward with the pre-filling of Income Tax Returns to make compliance more convenient for individual taxpayers.

(b) e-Verification of Income Tax Returns

e-Verification of Income Tax Returns filed (but not e-verified) which have remained incomplete due to non-submission of ITR-V form for verification for AY 2015-16, 2016-17, 2017-18, 2018-19 and 2019-20 has been re-enabled upto 30-09-2020. Also the time frame for issuing intimation has been relaxed and such returns are to be processed by 31.12.2020.

(c) ITAT Ruling: Disallowance of "freebies" to doctors by relying on CBDT Circular dated 01.08.2012 not justified

The **Income Tax Appellate Tribunal** Mumbai has ruled in a case that the disallowance under the Explanation to 37(1) of "freebies" to doctors by relying on CBDT Circular No. 5 dated 01.08.2012 and the IMC (Professional Conduct, Etiquettes & Ethics) Regulation, 2002 is not justified. The Code of Conduct prescribed by the Medical Council is applicable only to medical practitioners/doctors registered with the MCI and does not apply to pharmaceutical companies and healthcare sector in any manner. The CBDT has no power to extend the scope of the MCI regulation to pharmaceutical companies without any enabling provision either under the Income Tax Act or the Indian Medical Regulations.

(d) Form 26AS (Annual Information Statement)

New Form 26AS (Annual Information Statement) effective from 01st June, 2020 (CBDT vide Notification No. 30/2020 dated May 28, 2020)

- Form 26AS will now be a complete profile of the taxpayer; and will also have mobile number, email ID and Aadhaar number of the taxpayer;
- This will be a live 26AS, as this will be updated regularly within 3 months from the end of the month in which such information is received, such as information relating to tax deducted or collected at source, Specified Financial Transaction (SFT), payment of taxes, demand and refund, pending proceedings and completed proceedings which may include assessment, reassessment under section 148, 153A & 153C revision, appeal etc.
- Further an enabling provision has been notified empowering the CBDT to authorise Director General of Income Tax or any other officer to upload in this form, information received from any other officer, authority under any law. Thus any adverse action initiated or order passed under any other law such as custom, GST, Benami Law etc. including information about turnover, import, export, etc will also be inserted in the form 26AS;
- Form 26AS will also provide information received by Tax Department from any other country under the treaty /exchange of information about income or assets of the taxpayer located outside India.

(e) TCS on sale of goods under new Section 206C(1H) in IT Act

Finance Act 2020 introduced a new sub-section (1H) under Section 206C in IT Act to curb and track usage of unaccounted money and will be effective from 1 October 2020. It prescribes that if a seller (being a person, whose turnover in the previous financial year exceeds Rs. 10 Crores) makes sale of "goods" whose value, either individually or in aggregate exceeds 50 Lakhs, the seller shall collect tax at source at 0.1% on the value of sale consideration exceeding 50 Lakhs from the buyer. The person responsible for collecting tax shall deposit the TCS amount within 7 days from the last day of the month in which the tax was collected. Every tax collector shall submit quarterly TCS return i.e., Form 27EQ in respect of the tax collected by him in a particular quarter. The section states that tax shall be collected on the consideration value exceeding Rs. 50 Lakhs only, which means that there is an exemption limit of up to Rs. 50 Lakhs (individually or in aggregate on sales during any financial year). Export of goods is not covered under TCS on sale of goods.

R&D on Covid-19 Vaccines and Drugs as CSR

Mr Barve informed that the Ministry of Corporate Affairs has amended [vide G.S.R.526 (E) dated 24 August 2020] the CSR Rules 2014 to allow companies engaged in R&D activities for new vaccines and drugs to treat such expenses as CSR activities. It will cover financial years of 2020-21, 2021-22 and 2022-23. R&D will have to be undertaken in collaboration with organisations such as ICMR, DBT, DST, DOP, Ministry of AYUSH etc.

New Compliance Information Portal for Imports and Exports

Mr Barve informed that CBIC has developed a Compliance Information Portal for Imports and Exports which provides information related to Laws, step by step Procedures and Acts of Customs and all Partner Government Agencies (PGAs) regulating Import and export of commodities on a single portal.

Webinar on 'GST, Customs & Income Tax Implications on the Pharmaceutical Industry'

Mr Barve informed that IDMA had partnered with Lakshmikumaran & Sridharan (L&S) law firm and organised a Webinar on "GST, Customs & Income Tax Implications on the Pharmaceutical Industry". The Webinar had 627 persons registered and 397 persons participated who benefitted from the presentation and clarifications on key issues by the L&S attorneys. Members appreciated the same.

Developments in Income Tax and GST matters

National President informed that, on 21 October, the Finance Ministry had approved Guidelines for a Scheme for grant of ex-gratia payment of the difference between compound interest and simple interest for six months of loans up to Rs 2 crores. The Guidelines came after the Supreme Court directed the Centre to implement "as soon as possible" interest waiver on loans of up to Rs 2 crore under the RBI moratorium scheme in view of the COVID-19 pandemic. Borrowers having loan accounts with sanctioned limits and outstanding amount of not exceeding Rs 2 crores (aggregate of all facilities with lending institutions) as on February 29 are eligible. The scheme can be availed by borrowers in specified loan accounts for a period from March 1 to August 31, 2020. He requested Mr B G Barve, Chairman, Excise and Taxation Committee to brief Members on the recommendations of the 42nd GST Council Meeting and other developments in GST and IT. Mr Barve informed key points as below:

- One-time relaxation in implementation of E-Invoice system for the month of October 2020 was provided for trial runs to familiarise with the system. IDMA had requested the GST Council for extension of due dates till 31st March 2021
- Last date for submission of GSTR 9 and GSTR 9C is now 31.12.2020. IDMA had requested the GST Council for extension of due dates till 31st December 2020.

He informed that, as National President has mentioned, the 42nd GST Council Meeting was held on 5 October 2020 and some key decisions were as below:

- Levy of Compensation Cess to be extended beyond the transition period of five years i.e. beyond June, 2022, for such period as may be required to meet the revenue gap.
- Due date of furnishing quarterly GSTR-1 by quarterly taxpayers to be revised to 13th of the month succeeding the quarter w.e.f. 01.01.2021.

- Roadmap for auto-generation of GSTR-3B from GSTR-1s by Auto-population of liability from own GSTR-1 w.e.f. 01.01.2021, and Auto-population of ITC from suppliers' GSTR-1 through the newly developed facility in FORM GSTR-2B for monthly filers w.e.f. 01.01.2021 and for quarterly filers w.e.f. 01.04.2021.
- Refund to be paid/disbursed in a validated bank account linked with the PAN & Aadhaar of the registrant w.e.f. 01.01.2021.

On the developments in Income Tax provisions, he informed as below:

- Rule 5 of Income Tax Rules, 1962 has been amended to include 115BA, 115BAA, section 115BAB, section 115BAC and section 115BAD, thereby a person opting for a lower tax regime cannot claim depreciation allowance more than @40% for any block of assets
- Filing of original or revised income tax returns for F.Y. 2018-19 has been further extended to 30th November, 2020
- Income Tax Return filing for F.Y. 2019-20 has been further extended to 31st January, 2021
- Tax Audit Report filing for F.Y. 2019-20 has been further extended to 31st December, 2020
- Payment of tax without additional amount under Vivad se Viswas Scheme has been further extended to 31st March, 2021

Fall Clause - DOP directions to other Ministries

National President informed that DOP finally issued directions on 12 November 2020 to other Ministries in the procurement of drugs through tender clearly stating that Fall Clause does not apply on the sale of drugs, which have an expiry date. DOP has also instructed procurement agencies to ensure that tenders are issued in adherence with given instructions under Manual of Procurement of Goods, 2017. The Manual clearly states that the provisions of Fall Clause will not apply to "Sale of goods such as drugs, which have expiry date". He requested Mr B G Barve, Chairman, Excise & Taxation Committee to brief Members and also update them on recent issues in GST and IT.

Mr Barve informed that we have been following up with DOP, Ministry of Finance, NITI Aayog etc on the issue of fall Clause for the last few years. We had been following up Dr Vaghela on this matter and at our interactive meeting with DOP Secretary Ms S Aparna, we had again requested that other Ministries and procurement agencies be directed to comply with this requirement. Many of our MSME Members are dependent on tenders and this will boost their chances of procuring tenders at fair prices from central Government.

SC direction on Hand Sanitisers

Mr Barve informed that the Supreme Court directed a petitioner challenging the levy of GST on hand sanitizers under the same Tariff Heading as insecticides etc to file the petition in the High

Court. The controversy revolved around the levy of GST on sanitizers primarily concerned with two Tariff Headings i.e. 3808 and 3004. The Headings 3808 relate to disinfectants, apart from insecticides, herbicides, plant-growth regulators, etc. and attract GST rate of 18%. However, the Heading 3004 relates to Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses and attracts the GST rate of 12%. The sanitizer manufacturers or importers had stressed on the need to reclassify sanitizers as "Medicaments" given that it was being used as a protection from Coronavirus. The Union Finance Minister on the other hand had clarified in July that hand sanitizers were "disinfectants" like soaps, antibacterial liquids, etc. which attract 18% GST. The bench consisting of Justice Khanwikar, Justices B. R. Gavai, and Justice Krishna Murari, while granting the liberty to move the appropriate forum said, "this is an issue of classification of items under different heads. That is case-specific and a general direction cannot be issued. Whether sanitizers, insecticides etc should be classified in one head would depend on contents and other factors. Go to the High Court, if you want. We cannot issue a writ in this matter".

IDMA suggestions on Union Budget 2021-22

Mr Barve informed that as requested by DOP and Ministry of Finance, we have submitted our suggestions on amendments in Income Tax and GST on 12 November 2020. We have raised the issue of our Members facing regulatory challenges and tremendous pressure about applicability of GST rate 12% or 18% on Hand Sanitisers, not putting any restriction on claiming ITC for promotional items as brand reminders, or allowing ITC on Physicians samples as long as the goods are given free of cost and Free Samples are for business purposes, 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 more years under section 35(2AB) of IT Act.

GST & IT Updates

Mr Barve informed as below:

(a) GST matters

Last date for submission of GSTR 9 and GSTR 9C is now 31 December 2020. Taxpayers having aggregate turnover of up to Rs 5 crores are not required to furnish GSTR 9C for F.Y. 2019-20;

CBIC has now notified that an invoice issued by a registered person, whose aggregate turnover in a financial year exceeds Rs 500 crores, other than those referred to in sub-rules (2), (3), (4) and (4A) of rule 54 of said rules, and registered person referred to in section 14 of IGST Act, 2017, to an unregistered person, shall have Dynamic Quick Response (QR) code from the 1st day of December, 2020.

Also now, a registered person whose aggregate turnover in any preceding financial year from 2017-18 onwards exceeds Rs 500 crores as a class of registered person shall prepare invoice and other prescribed documents, in terms of sub-rule (4) of rule 48 of

the said rules in respect of supply of goods or services or both to a registered person or for exports.

(b) IT matters - Amendments in Form 26AS

This year CBDT has introduced Form 26AS in new format with a few amendments. Form 26AS earlier used to give information regarding TDS and TCS besides certain additional information including details of other taxes paid, refunds and TDS defaults. But now it will have SFTs (Statement of Financial Transactions) to prompt the taxpayers about their major financial transactions as a ready reckoner while filing the ITR. Form 26AS will have all the information on taxes paid by a taxpayer, details of pending as well as completed income tax proceedings, status of income tax refund and demand along with details of specified financial transactions like purchase of shares or property. The format of Form 26AS has also been enlarged and amended to include information received from other departments/ agencies, including the GST authorities and thus will also reflect GST returns information. Hence Members have to be careful while filing GST and IT Returns.

Finance Ministry Pre-Budget meeting for Union Budget 2021-22

National President informed that, following our detailed submission on Income Tax and GST matters for the Union Budget 2021-22, Ministry of Finance invited us for online discussions on 11 December 2020. Mr B G Barve, Chairman, Excise and Taxation and his Committee Members Mr Prakash Rijhwani and Mr Vijay Bhatt represented IDMA along with Mr Ashok Madan. He requested Mr Barve to brief Members. Mr Barve informed that IDMA was given special consideration and were the first Association to be invited for discussions which lasted for an hour. Mr. Ajit Kumar, Chairman CBIC, Mr. Vivek Johri, Special Secretary & Member, GST and senior officials were present. OPPI representatives were also present. We made a number of suggestions such as:

- Maximum rate of depreciation from FY 2018-19 for all medical/surgical/pathological equipments including life - saving medical equipments is 40% and should be increased to 60%
- Currently, India imports 80%-90% APIs from China. it is recommended to formulate policy/ scheme on a priority basis to boost manufacturing of APIs in India, which Government has already initiated with PLI schemes for APIs and Bulk Drug parks. With introduction of new section 115BAB, the reduced tax rate of 15% is available to only those units which are set up on or after 01-10-2019. However, we have suggested that such progressive outlook be extended to any new investment even in an existing business with suitable safeguards and provisions of law.
- Section 35 (2AB) Weighted Deduction for R&D of 200% needs to be restored and continued for another 10 years to give impetus to R&D and will help in the robust growth of the economy.
- R&D benefit may also be extended to those companies, who had availed the exemption under lower rate of IT Act.

- Freebies are purely business expenditures and ITC should be permitted.
- ITC may also be allowed on Free samples, as revenue loss to the Government is minimal but this will be of great help to industry.
- Donations of medicines for natural calamities should be allowed under IT Act
- IDMA Members manufacturing hand sanitizers are facing regulatory challenges and tremendous pressure about applicability of GST rate 12% or 18%. The MRP itself was fixed based on the GST at 12% as a drug product. At this juncture, it is not possible for the members to bear any additional impact of GST or to face the pressure being mounted by GST Intelligence and the GST Department in seeking payment of the higher rate of GST.
- Aerosol therapy spray pumps – we referred to interpretation under Chapter 96 and requested for consideration of these devices under Chapter 90. Medical devices are not covered under Chapter 96.
- Many other GST related issues were discussed in detail related to our Industry.

REPORT OF IPR COMMITTEE

IDMA case in Delhi HC on IPAB Technical Member - Patents issue

The Intellectual Property Appellate Board (IPAB), a quasi-judicial Tribunal which, among other things, oversees functioning of patent matters is headed by a Chairperson who under the law has to be a retired High Court Judge or equivalent. The Patents Bench needs to comprise of a Judicial member and a 'Technical Member Patents'. IPAB was functioning without legally appointed Technical Member Patents. The Chairperson of the IPAB did not have the statutory powers to appoint a Technical Member Patents. This is a statutory post, and has to be filled in by the Ministry based on an established system of selection process. Alternatively, either the High Court or the Supreme Court could do so. Since the matter was in the best interest of all IDMA members, we approached Delhi High Court to direct DIPP to form a panel of retired Controllers' of Patent to carry out the functions of Technical Member Patents as an interim measure.

Following our appeal, the appointment of the Technical Members was placed on record by the Union of India before the Delhi High Court and in recognition of our appeal, the IPAB fulfilled the requirements of streamlining the Board. Mr Birendra Prasad Singh, Joint Controller of Patents and Designs was appointed as Technical Member for Patents in Intellectual Property Appellate Board (IPAB). Ms Lakshmidevi Somanath, Advocate and Mr. Vijay Kumar, Advocate/ Patent Agent were appointed as Technical Members for Trademarks. Mr N. Surya Senthil, Advocate and Mr S.P. Chockalingam, Advocate were appointed as Technical Members for Copyright. It was heartening to note that almost all the Technical Members were well-qualified and young, and would be able to serve for many years in the IPAB.

In a hearing in September 2020 in Supreme Court on the appeal by the International Association for the Protection of Intellectual Property (AIPPI) for extension of Mr. Justice Manmohan Singh as

Chairperson of the IPAB for one year beyond 21st September, 2020, the Court allowed extension only for a period of three months. AIPPI were reportedly in favour of MNCs and patent monopoly. Further extension to Mr. Justice Manmohan Singh has been refused by the Supreme Court. In the meantime, the Hon'ble Finance Minister, Mrs. Nirmala Sitaraman has moved a bill in Parliament for abolition of IPAB, appeals will be heard by the commercial Benches of High Court.

MSF urges government to include patented drugs in upcoming NLEM

MSF (Médecins Sans Frontières – Doctors Without Borders) requested Government of India to include patented as well as non-patented drugs in the upcoming NLEM. MSF requested that inclusion in NLEM should not be linked to patent status, as essentiality of the medicine cannot be determined by its patent status. MSF also pointed out that exclusion of patented drugs from price control undermined right to affordable lifesaving essential medicines under Article 21 of the Indian Constitution. DOP had amended para 32 of DPCO 2013 in January 2019 to allow drugs patented in India to be kept out of price control for 5 years. The conditions for the drug to be "not produced elsewhere, if developed through indigenous Research and Development" was removed. This would allow MNCs monopoly by merely importing the patented medicine and market at a high price. MSF also suggested that the new antibiotics for drug-resistant tuberculosis such as Bedaquiline and Delamanid be included in NLEM as they were already part of WHO EML. Another suggestion was facilitating the administration of insulin as well as different formulations of insulin such as pen devices, insulin in cartridges etc to be added in the upcoming NLEM.

India and South Africa seek waiver from WTO on COVID-19 prevention and treatment

In a landmark move on 2 October 2020, India and South Africa sought a waiver from WTO to allow all countries to choose to neither grant nor enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics and other technologies for the duration of the pandemic, until widespread vaccination was in place globally, and the majority of the world's population had developed immunity. This bold step, when approved, could be a historic turning point in the countries' response to the pandemic. The proposal came up before the TRIPS Council meeting on 16 October, though a decision was not taken due to the absence of consensus among members.

Trademark Registration of 'IDMA' name and logo

Republic TV and some digital media formed Indian Digital Media Association and publicised it as IDMA. As we are already known as IDMA, this could create confusion and repercussions. Though IDMA was formed in 1961, we had not felt it necessary to register our logo and name, Over the years, there have been others who have been identified similarly as IDMA. Though it is not compulsory to register a Trademark, Indian Trademark law statutorily protects trademarks only if registered. As our Trademark 'IDMA' was not registered, the Courts would not recognise it as our Intellectual Property. A Resolution was taken up and passed unanimously at the Executive Committee meeting on 30 October 2020 as below:

"RESOLUTION

RESOLVED THAT Indian Drugs Manufacturers' Association adopted the trade name and logo 'IDMA' (Device) in 1961 and desires to register the same under the Trade Marks Act, 1999 with respect to the goods and services covering under three Classes, i.e. Class 16, 35 & 41 with suitable descriptions of the activities of the Association.

RESOLVED THAT the Executive Committee of the Association, in its meeting held on 30th October 2020, authorize Mr. Daara B. Patel, Secretary-General of Indian Drug Manufacturers Association (IDMA) to do and perform any and all such acts, including execution of any and all documents and certificates to complete the registration formalities of the aforesaid trademark applications.

RESOLVED FURTHER THAT Mr. Daara B. Patel be authorised to assign the aforesaid assignment to GOPAKUMAR NAIR ASSOCIATES, IPR Attorneys to apply and prosecute the above applications on behalf of Indian Drugs Manufacturers' Association and to obtain grant of registration."

Proposed by: Dr George Patani
Seconded by: Mr Mahesh Doshi Date: 30 October 2020

The Resolution was adopted and passed unanimously. It was decided to register 'IDMA' as a Trademark under Class 16, 35 and 41 to stop others from using or misusing our name 'IDMA'. Later if required, it could be registered under Class 5 also. Dr Gopakumar G Nair, Past President and Chairman, IPR Committee graciously offered his services *pro bono* for this cause and applied for the Registration.

Office of Controller General of Patents

Mr Om Prakash Gupta, IAS, Controller General of Patents, Designs & Trade Marks vacated his office and Shri Rajendra Ratnoo, IAS, Joint Secretary, DPIIT has been officiating in his place.

Dapagliflozin Patent Infringement – Delhi High Court declines Injunction to AstraZeneca

On 2nd November, 2020, Hon'ble Mr. Justice Rajiv Shakdher of the Delhi High Court passed a remarkable Order in Dapagliflozin infringement suit giving big boost to patients and generics. Just like in the case of Erlotinib wherein Hon'ble Mr. Justice Ravindra Bhat took into consideration "public interest", Hon'ble Mr. Justice Rajiv Shakdher also endorsed "public interest" while noting that the difference in prices of drugs ranged between 250% to 350%. Hence, the Defendants Intas Pharmaceuticals Limited and Alkem Laboratories Limited were allowed to manufacture and market generics which would be far cheaper. The Court also noted the admission by the Plaintiff AstraZeneca in several paragraphs of the Plaint including the Prayer that Dapagliflozin was covered

by the claims of genus patent IN 147. Hence, the entire principal claim of IN 625 was vulnerable to revocation. While refusing to grant interim injunction against Intas and Alkem, they were directed to place on Court's record every quarter the details, quantum, and value of drug manufactured and sold as also indirect and direct taxes paid in that behalf. Following this Order, Hon'ble Ms. Justice Mukta Gupta passed a follow up Order on 18 November 2020 disposing all similar cases by AstraZeneca against Torrent Pharmaceuticals Ltd., Micro Labs Limited, Zydus Healthcare Ltd., Eris Lifesciences Ltd., USV Pvt. Ltd. and MSN Laboratories Pvt. Ltd. This allowed manufacturing and marketing of Dapagliflozin as a generic in India, subject to other conditions such as filing of statements of such accounts on quarterly basis in the Court, certified by their auditors with advance copies to the plaintiffs etc.

Patent (Amendment) Rules 2020 notified

Patent (Amendment) Rules 2020 were notified consequent to circulation of draft rules and reviewing of responses received. One welcome amendment was on Working of Patents in India. Form 27 was amended and notified as originally proposed for amendment. The Working of Patents in India would henceforth be hopefully pursued more seriously and diligently than before, with the revised data in Form 27 being sought for approval.

The Rules have been amended with reduced Fees to be paid by small entities for various filings. Start-ups were already allowed reduced fees. One favourable amendment was also that a request for expedited examination filed by a startup or small entity would not be questioned merely on the ground that the startup or small entity, having filed an application for a patent, ceased to be a startup or small entity due to the lapse of the period during which it was recognised by the competent authority, or its turnover subsequently crossed the financial threshold limit.

REPORT OF INTERNATIONAL TRADE (INCLUDING CUSTOMS) COMMITTEE

Restrictions on Exports 13 APIs and its Formulations lifted

DGFT had issued a notification dated 3rd March 2020 restricting export of 13 APIs such as Paracetamol, Tinidazole, Metronidazole, Acyclovir, Vitamins B1, B6, B12, Progesterone, Chloramphenicol, Erythromycin, Neomycin, Clindamycin and Ornidazole and its formulations. We made an urgent submission on 6th March requesting that for lifting of the restrictions, as industry had ensured that stocks were available in market and supply chain for 2 to 3 months and also ensured continuously required supply of these medicines in the domestic market. We also had regular interactions with Government on this matter. Government heard our request and withdrew the restrictions allowing exports to continue on all the drugs except Paracetamol.

Hydroxychloroquine (HCQ) and Paracetamol

Export of key malaria drug Hydroxychloroquine (HCQ) and Paracetamol were prohibited by Government in order to ensure that it was available for domestic use. As there was global demand for HCQ for boosting immunity against Coronavirus, we requested Government in our interactions and also through TV, social media etc to allow boosting of production capacities to fulfil local and global commitments. Also, there was increased demand in quantity from certain countries as they regularly depended on India to supply these drugs. Some drugs were considered suitable for repurposing in boosting immunity against COVID-19 such as HCQ, Azithromycin, Remedesivir, Lopinavir + Ritonavir, is a combination of two HIV drugs, etc. Government allowed export after the manufacturers committed to ensure buffer supply for local requirements before exports. State FDAs also supported and manufacturers were allowed to export HCQ and Paracetamol to fulfil export commitments.

Following a request by US President Donald Trump, India exported 50 million tablets of HCQ to USA as a possible treatment and immunity booster for COVID-19. This was India's biggest export of HCQ to any country and India also supplied HCQ and other essential medicines to many other countries on humanitarian grounds and also on commercial basis. Following our repeated requests to Government, DGFT issued a notification on 18 June 2020 lifting all restrictions on export of Hydroxychloroquine API and formulations. DOP had also written to Commerce Ministry in support of Industry's request for lifting the ban.

Proposed 15% COVID-19 tax on chemical imports from China

Chemexcil had reportedly proposed to Government to impose 15% COVID-19 tax on all chemical imports. The proposal appeared to have been made by the Department of Chemicals and Petrochemicals (DCPC) on specific Chapters 28, 29 and other related Chapters which was accepted by Chemexcil. This required to be countered as prices of many chemicals were already very high and it could hike the prices further. It would have also been counter productive and could have led to non-availability of many chemicals. We made a submission on 30th April 2020 to DCPC not to impose the COVID-19 tax broadly chapter-wise for the reasons cited above and if required, it could be considered on selected Chemicals.

Track and Trace of Pharma Export packs

DGFT issued a Public Notice [No. 66/2015-2020 dated 30 March 2020] extending implementation of Track and Trace system for export of Pharma packs and maintaining of parent-child relationship in packaging from 1 April 2020 to 1 October 2020. DGFT on 22 September 2020 issued another Public Notice extending implementation date to 1st April 2021. We attended the Expert Committee meeting held in August 2020 and also made a submission on 24th August requesting that the Track and Trace system may be kept in abeyance or at least the implementation date be extended for one year till 1st October 2021.

Interest Equalisation Scheme (IES) for MSMEs for Pre and Post Shipment credit

As per Foreign Trade Policy (FTP) 2015-2020, initial Interest Equalisation of 3% was increased to 5% with effect from 2nd November 2018 in respect of exports by the MSMEs and was to be availed by MSMEs till the term of FTP policy. DGFT had already extended the FTP term for one year till 2021, but RBI had not notified the banks on the same. In absence of RBI circular for extension of the Interest Equalisation Scheme (IES) to the banks, MSMEs were being charged full interest rate by banks @ PLR and no benefit was being passed on to the MSMEs as was prescribed in the Trade Notice No. 45/2018-19 dated 1st February 2019. We made a submission to Finance Secretary on 10 April 2020 to recommend to RBI to immediately issue circular for extension of IES. Following our representation, DGFT issued Notices notifying that the IES was extended for pre and post shipment Rupee export credit for one more year i.e. upto March 31, 2021, to assist MSMEs to avail the 2% additional benefit which was being provided to them.

MEIS incentive Scheme and RoDTEP

The MEIS Incentive Scheme which was available to Exporters was being discontinued from 1st January 2021 due to certain objections raised by WTO on incentives offered to Exporters. Government then decided to determine the cost of indirect taxes & duties which exporters were incurring in manufacture and distribution of their products within India, so that the same could be compensated as reimbursement to offset the imbalance of cost structure in India vis-à-vis other exporting countries. The exporters were required to study their cost structure in detail for determining the indirect and hidden embedded taxes and duties in their entire operations, from procurement till export out of the country, to be compensated through RODTEP, which could work out to about 3% of their costs. Necessary formats provided by CBIC as R1, R2, R3 seeking inputs on taxes, costs incurred were forwarded by email to all Members. Exporters were requested to study their cost structure in detail for determining the indirect and hidden Duties and Taxes in their entire operations, from procurement till export out of the country. These embedded taxes would be compensated through RODTEP. For the benefit of our Members, we had invited Mr Bhaskar Thakkar, CEO, BT Associates, an expert in Indirect Taxation who addressed us on how to calculate for seeking a reasonable percentage of compensation. Later, as Members were still unsure on how to calculate, Mr Thakkar offered to help IDMA members on a complimentary basis regarding queries related to Indirect Tax difficulties, GST, etc till 31st December 2020. As it had become apparent that MEIS would be discontinued from 31 December 2020, with even the Hon'ble Minister of Commerce and Industry not agreeing to provide any extension beyond 31 December 2020, exporters faced a loss of export benefits of 3%. Hence it was urgent that a large number of Members submit their data for RoDTEP with at least 3 or more stages of the supply chain to enable Government to fix 3% as available under MEIS. In the absence of timely inputs from Members, the Committee would be forced to take decision based on the limited data available and fix the ceiling rates accordingly.

Funds allocated for MEIS

CBIC had issued an OM dated 12 November 2020, that in response DGFT's various requests, Government approved allocation of Rs. 39,097 Crores for MEIS benefits for exports made during FY 2019-20 and another Rs. 15,555 Crores for MEIS benefits for exports made during the period 01.04.2020 to 31.12.2020. Further, the allocation was to be utilized for issuance of duty credit scrips only for exports made during the respective periods i.e Rs. 39,097 Crore for FY 2019-20, Rs. 10,555 Crore for the period 01.04.2020 to 31.08.2020 and Rs. 5000 Crore for the period 01.09.2020 to 31.12.2020. However the window for accepting applications for MEIS scrips for the period from 1st April 2020 to 31st December 2020 has not yet opened. IDMA continues to pursue the same with the Ministry and DGFT.

RBI reply to IDMA representation on import of Palladium and other precious metals by pharma industry

National President informed that we had made a representation on 10 July 2020 to RBI Governor Shri Shaktikanta Das, IAS to allow import of Palladium and other precious metals on Advance Payment used in production of Drugs and Pharmaceuticals (which was published in IDMA Bulletin dated 30 July 2020). RBI replied to our submission on 30 July 2020 seeking specific details of the cases that were declined by RBI as referred in our letter. We immediately submitted the same. We later received an advisory email from RBI on 7 August 2020, stating that "We advise you to inform your members to approach the Regional Offices concerned of RBI through their respective AD banks with such requests." This Advisory has been published in IDMA Bulletin dated 14 August 2020.

Streamlining of UQCs in DGFT's EDI system and Customs' ICEGATE

National President informed that Mr C V Venkatraman brought to our notice about issues in export due to Jawaharlal Nehru Customs House (JNCH) suddenly issuing a Public Notice specifying limited Unit Quantity Codes (UQCs). We immediately made an urgent representation on 11 September 2020 Ministry of Commerce, DGFT and JNPT highlighting the issues and requested DGFT to defer implementation of the Notice seeking time to complete the pharma export orders. DGFT reacted promptly and issued a Trade Notice dated 14 September 2020 allowing exports to continue based on the Unit of Measure (UOM) such as BoU, packs, boxes, cartons, bottles etc as practiced by Pharma Industry till 30 October 2020. The usage of harmonized standard UQC at the time of filing of Shipping Bills and Bills of Entry in ICEGATE was being carried out by DGFT and Customs Departments, for standardisation in the data collection for the purpose of clean data reporting and analysis. In the meanwhile, Advance and EPCG authorization holders were requested to approach concerned RA and get the non-standard units indicated in their authorizations in the import and export quantities, converted to standard quantity units. Our representation was published in IDMA Bulletin dated 14 September 2020 along with the JNCH Public Notice specifying the UQCs.

Validity of Registration Certificate and Import License extended

The Ministry of Health and Family Welfare issued a notification [G.S.R. 2450(E) dated 27 July 2020] extending validity of Registration Certificate issued under Form 41 for 6 months. This was made for ease of doing business in view of the COVID-19 pandemic. As there was no mention of similar extension of validity of Form 10 licence, we sought a clarification from DCG(I) whether Form 10 licence issued against Form 41 would also be considered similarly valid for 6 months, so that importers would not need to apply again to get Form 10 to avoid duplication of work. The Ministry of Health and Family Welfare issued a notification [G.S.R. 4244 dated 26 November 2020] extending validity of Import Licence under Form 10 notifying that "notwithstanding anything contained in rule 28 of the Drugs and Cosmetics Rules, 1945, for import of drugs for sale or distribution, if an existing valid import licence holder under the said rules, makes an application for a fresh import licence before the expiry of the existing licence, the existing import licence shall be valid until orders are passed on the application and shall be deemed to be valid for all purposes".

Trade hit by 60% surge in freight – inputs sought by Department of Commerce

Trade, both exports and imports, was severely impacted in September and October 2020 after sea freight charges were increased by over 60%, mainly by shipping companies. The hike in rates impacted pharma industry and all other industries. There was an increase in freight costs of 20-30% in October alone. Air freight was also up by 30-40% owing to reduced overseas flights due to the COVID-19 pandemic. For importers, along with the increased freight rates, there was a higher outgo in terms of duties, which could impact companies' margins in future. Exporters were also facing a massive shortage of containers due to lower imports over the last few months. The Logistics Division of Department of Commerce received several representations regarding the shortage of empty containers for exports. The Division interacted with the Container Shipping Lines Association (CSLA) and the stakeholders on this matter. The Logistics Division requested IDMA Members to forward them the projection of the requirement of containers for the next two months. We sent an email circular to all Members on 26 October seeking their requirements of empty containers during November and December 2020 to be filled in a format as provided by the Department. At a meeting with Pharmexcil, Shri Piyush Goyal, Hon'ble Minister of Commerce and Industry agreed to take up the matter with Secretary of Shipping. He also spoke to Hon'ble Minister of Shipping Shri Mansukhlal Mandaviya, who was also the Minister of Chemicals and Fertilisers and hence responsible for Pharma industry. Over 50,000 containers were reportedly stuck in various Ports. Government was upset about shipping companies taking undue advantage of the situation and considered inviting shipping companies from Middle East to ease the situation. They also suggested that containers that were not cleared from the Ports within six months would be auctioned.

Meeting with Commerce Minister and submission of Representation on New FTP

DGFT issued a Trade Notice on 12 November 2020 seeking inputs and suggestions for preparing a new Foreign Trade Policy. FTP 2015-20 was earlier extended by a year till 31 March

2021. A Video Conference was organized with Shri Piyush Goyal, Hon'ble Minister of Commerce & Industry and stakeholder Associations of many industries were invited to discuss the shaping of new Foreign Trade Policy. We informed the Hon'ble Minister that since RoDTEP for pharma sector may not be available from January 2021, we request continuation of MEIS at least till the RoDTEP was implemented. We also suggested the following:

- In case a pharmaceutical intermediate is imported by a manufacturer of APIs located in DTA under Advance Authorisation (AA), and the relevant API is sold to SEZ unit, since the invoice is in INR, SEZ unit has to pay to DTA in INR and cannot pay through FCA. Thereby, the DTA importer cannot close obligations under the AA of the intermediate so imported and this leads to litigations. We have requested that Para 4.21, Sub para (iii) be removed and Sub para (iv) be amended to read as "Export to SEZ units/Developers/Codevelopers can also be taken into account for the discharge of export obligations"
- Though it was accepted that Pre-import and Physical exports condition in AA need to be removed, the Notifications do not address the period from 13.10.2017 and 10.01.2020. AA before and after this period are however covered. We have requested that the New FTP should not include the clauses for Pre-import and Physical Export conditions for Advance Authorization. We also submitted that DGFT Notification No 53/2015-2020 and Customs Notification No. 01/2019 both dated 10.01.2019 may be amended to give effect for the period 13.10.2017 onwards.
- Many countries do not recognize the GMP issued by Indian regulatory Authorities under the WHO GMP scheme and create a Non-Tariff Barrier for the entry of Indian medicines. This slows down the entry of Indian medicines in such markets. We have requested that while signing FTAs, India may also add Mutual Recognition of GMP issued by Indian Authorities as per the WHO GMP Inspection Scheme for products moving into international trade.
- Though interest subvention of 3% is valid till 31 March 2021, it may be extended and subvention raised from 3 to 5%.
- Incentives should be given on incremental exports, especially for the Pharma sector. Also, Pharmaceuticals may please be included in the Scheme for promotion of Incremental Exports under the new FTP.
- To reinstate 36 months' time period for Advance Licenses (currently reduced to 18 months).
- Though environment approvals are not a part of the current subject, still quick environment clearance is very important for exports of APIs.
- Also, environment permission should be given to "APIs together with Intermediates" as a category rather than a single API.

The Hon'ble Minister was aware of the issues and responded to most of our suggestions. We also made a written submission on 14 December 2020 listing our suggestions for the New FTP.

Ministries of Commerce & Industry and AYUSH to set up AYUSH Export Promotion Council

Ministry of Commerce and Industry and the Ministry of AYUSH decided to work together to set up an Export Promotion Council to boost AYUSH exports. This decision was taken in a joint VC review of AYUSH Trade and Industry on 4 December 2020 by Shri Piyush Goyal, Hon'ble Minister of Commerce and Industry and Shri Shripad Naik, Hon'ble Minister of AYUSH. The AYUSH Minister informed that the emerging evidence of correlation between the low COVID-19 mortality rates and largescale adoption of AYUSH prophylactic solutions by the population was significant for the public health practice in the country. The protection offered by the AYUSH systems to the common people during the pandemic time neutralized the doubts that many people had about the efficacy of the medicines and products offered by these systems. The Commerce Minister informed that the spurt in exports of AYUSH products in the recent months was a direct reflection of their growing popularity in many countries. The standardization of the HS codes related to export would be considered on priority as a step to promote exports and AYUSH would be included in the Brand India activities

Export Rules eased by RBI

Reserve bank of India (RBI) announced certain measures on 4 December 2020 to ease procedures for exporters as below:

- Some procedures that required approval of the central bank were removed, allowing banks to decide on their own. Banks till then did so in the case of exports of up to $1 million. Above this threshold, the RBI's intervention was required in case documents were directly shipped by exporters to the buyers.
- Banks were allowed to regularize exports where proceeds were realized. Status-holder exporters were allowed to send documents directly to buyers but others could do so only in the case of advance payments. Many exporters were digitally sending documents and getting payments from exporters as the COVID-19 pandemic made it difficult to access courier services.
- RBI also permitted banks to write off export bills without any limits in case overseas importers were declared insolvent or goods were destroyed by Customs and other authorities abroad. The write-off facility, till then, was available only to the extent of 5 per cent of export value for normal exporters and 10 per cent in the case of status holders.
- RBI also permitted banks to allow groups to set off their receivables against the money to be paid to the same importers. This was available only to companies, but was extended to groups.
- Banks were allowed to consider refund requests without insisting on import of goods, which were perishable in nature or had been auctioned or destroyed by the authorities concerned, subject to production of documentary evidence.

Iran Rupee Trade settlement

RBI had issued a Circular on 6th August 2020 to all Scheduled Commercial Banks and Payment Banks, instructing them to follow discipline in opening of current accounts and advised Banks not to open current account for customers who have availed credit facilities in the form of Cash Credit (CC) or Overdraft (OD) from the banking system. Many of our members export Bulk Drugs and Medicines to Iran under rupee payment mechanism for trade settlement through IDBI and/or UCO bank by opening a current account with them. We made an urgent submission to Chief General Manager-in-Charge, RBI New Delhi on 10 December 2020 on issues in Iran Trade settlement through current accounts. The RBI circular was silent on settlement of Iran related trade by Indian banks and the existing Scheduled Commercial Banks who provided CC/OD facility were advising manufacturers to close current account with IDBI / UCO bank. We requested RBI to provide necessary clarification to all the Scheduled Commercial Banks and Payment Banks to continue to allow companies to maintain current account with IDBI and/or UCO bank for Iran Trade settlement.

REPORT OF MARKETING COMMITTEE

'Marketer' defined under D&C Rules

National President informed that the Ministry of Health and Family Welfare issued notification (G.S.R. 101 dated 11 Feb 2020) to define 'Marketer' under Drugs and Cosmetics Rules to be effective from 1st March 2021. Under this Rule, the Marketer would be held responsible for ensuring quality and regulatory compliances of the marketed drug. However, this would apply only when the Marketer's name was printed on the label along with the manufacturer's and the Marketer may not be held liable if his name was not included in the label. Mr S M Mudda, Chairman, Regulatory Affairs Committee informed that we had made a detailed submission on 24 July 2019 highlighting the legal aspects and impact on cost and availability of drugs. We suggested that the responsibility for quality and regulatory compliance cannot be placed on the marketer grossly and had to be specified clearly. Also the definition of 'Marketer' as notified would need to be modified to remove the words 'agent', as the Marketer worked on a P-to-P contract basis.

Webinar/Seminar on Marketing Strategies Post-COVID-19 lockdown

National President suggested that we may consider organising a Webinar on Marketing Strategies Post-COVID-19 lockdown as proposed by Mr Vinay Pinto, Chairman, Marketing Committee. He requested Mr Vinay Pinto, Dr George Patani, Mr Mehul Shah and Mr Manish Doshi to work on the modalities for organising this event.

Glenmark, Cipla and Hetero launch drugs in India for treatment of COVID-19

National President congratulated Glenmark for becoming the first pharmaceutical company in India on 29 June 2020 to receive regulatory approval for oral antiviral Favipiravir for the treatment

of mild to moderate COVID-19. Glenmark was granted manufacturing and marketing approval as part of accelerated approval process to market the antiviral under the brand name FabiFlu. The approval's restricted use requires every patient to sign informed consent before treatment. He also congratulated Cipla and Hetero for launching their versions of Remdesvir, approved by DCG(I) for the treatment of suspected or laboratory-confirmed cases of COVID-19 in adults and children, hospitalized with severe symptoms of the disease. Cipla launched Cipremi (Remdesivir lyophilised powder for injection 100 mg), US FDA approved Emergency Use Authorisation (EUA) treatment for patients with severe COVID-19 disease. Hetero launched Remdesivir under the brand name Covifor, being made available in 100 mg vial (Injectable) to be administered intravenously in hospitals.

UCPMP meeting

National President informed that a meeting to discuss UCPMP was organised by DOP through VC on 21st August, 2020 and chaired by Dr P D Vaghela, Secretary, DOP. Dr Viranchi Shah, Senior Vice President and Mr Ashok Madan represented IDMA. He requested Dr Shah to brief Members. Dr Viranchi Shah informed that NPPA Chairman Mrs Shubra Singh and other officials had also participated. Other Associations such as IPA, OPPI, CII, FICCI, etc were also represented. Associations of Medical Device companies such as AIMED were also present. Dr Vaghela thanked the Industry for the excellent job during the COVID period. He was concerned about the black marketing and hoarding of Remdesivir and Tocilizumab. After discussion he decided to get AIOCD actively involved. We informed that IDMA is the first association to upload UCPMP on our website, and forming of ETHICS and APEX Committees. We had made a detailed submission earlier on each clause of the UCPMP and submitted to DOP along with a note on global practices. We were informed that three complaints had been forwarded to the Association but no action had been taken. They will be forwarding the complaints again to us.

Dr Shah informed that DOP Secretary was requested by the Associations to keep the Code voluntary. It appeared from the discussions that he was also favourable in this matter. However, NGOs were pressurising Government to make it mandatory.

IDMA Marketing Committee Webinar

Secretary-General informed that a Webinar was organised by IDMA Marketing Committee jointly with NextPlan Consulting on "New Normal - Post COVID-19" on 8th August. The webinar was supported by AIOCD Pharmasofttech AWACS Pvt Ltd. There were over 450 participants.

UCPMP - NPPA Circular - RTI reply

National President informed that NPPA had issued a circular dated 26 August 2020 informing that they were working on timely disposal and monitoring of applications filed with NPPA. In the

circular NPPA had also listed UCPMP stating that the detailed procedure mentioned in para 10 of UCPMP about lodging of complaints, details of the company against whom complaint is made to the Association, action taken by the Committee under the Association etc will need to be uploaded on the Association website and a quarterly report mentioning details of the complaints received and decisions taken will need to be submitted to NPPA within 30 days. He requested Dr Viranchi Shah, Senior Vice-President to brief Members about the UCPMP meeting of DOP in which he had represented IDMA.

Dr Viranchi informed that, as discussed at the last meeting, a meeting to discuss UCPMP was organised by DOP through VC on 21st August, 2020 and chaired by Dr P D Vaghela, Secretary, DOP. The Secretary wanted all Associations to upload UCPMP on their websites and also form the Apex and Ethical Committees. As informed to DOP Secretary, we have already uploaded UCPMP and the two Committees on our website. Dr Shah informed that DOP Secretary was requested by the Associations to keep the Code voluntary.

He further informed that, replying to a question in Parliament on 18 September 2020, the Minister of Chemicals and Fertilisers Shri D. V. Sadananda Gowda had informed Parliament that there was no provision for DOP to directly deal with complaints received regarding unethical practices. As per UCPMP, any complaint received against a pharmaceutical company was to be handled by an Ethical Committee for Pharma Marketing Practices (ECPMP) to be constituted in each of the pharmaceutical associations. DOP has been following up with the pharma associations to implement the code effectively. In this regard, DOP had also taken multiple meetings with the pharmaceuticals associations and most of the associations have put UCPMP on their websites and constituted the Committees for handling complaints regarding breach of UCPMP.

National President further informed that, while replying to an RTI filed by one Mr K V S Lakshman, NPPA has stated that NPPA was not mandated [under the Resolution dated 20 September 1997 when NPPA was formed] to monitor the Pharmaceutical Marketing Practices.

(a) Responsibilities of Marketer

Mr Mudda informed that the responsibilities of Marketer for quality and regulatory compliance was notified vide G.S.R. 101 dated 11 February 2020. The Rule comes into effect on 1 March 2021. We had made a detailed submission on the draft notification issued last year highlighting the legal and regulatory compliance issues that would arise. However, the draft notification has been finalized without considering our suggestions. We have now made a submission dated 23 September 2020 - pointing out the various issues in implementing the Rule as under Section 19 (3), the Act provided relief to any person, not being the manufacturer of the drug or his agent from being liable for a contravention of manufacturing Rules. We have made suggestions on how to resolve the matter by revising the definition of Marketer, introducing a new section in D&C Rules, adopting the concept of Contract Giver and Contract Acceptor from EUGMP etc.

Letter from DOP on UCPMP Compliance

National President informed that we have received a letter from DOP informing us and other Associations that they have received a complaint alleging that pharma companies are sponsoring the National Conference of Indian Psychotropic Society in January 2021. They have requested all Associations to ensure that the companies adhere to the provisions of UCPMP. He requested Mr Vinay Pinto, Chairman, Marketing Committee to brief Members. Mr Pinto informed that, as provided in the UCPMP, the Ethical Committee for Pharmaceuticals Marketing Practices (ECPMP) and Apex Committee (ACPMP) were already formed by IDMA in February 2020 to take up any complaints received from the public. Members deliberated on this matter. It was discussed that DOP had received a vague complaint that alleged about pharma companies sponsoring a forthcoming Conference without any evidence. Members also were not aware of any organisation called the 'Indian Psychotropic Society'. After discussion, it was decided that there was no point in the Ethics Committee discussing this matter at present without further details. It was discussed that a meeting of the Ethics and Apex Committees may be called at the earliest so that DOP could be informed about the meeting.

REPORT OF MEDICAL COMMITTEE

New Drugs and Clinical Trials (Amendment) Rules, 2020

The Ministry of Health and Family Welfare issued a draft gazette notification [G.S.R. 354 dated 5 June 2020] proposing amendments to the New Drugs and Clinical Trials Rules, 2019. The amendment proposes to allow manufacturing, import etc of any new unapproved drug for Compassionate use even when the drug is not approved for marketing in India. A medical officer of a hospital or any medical institution can recommend a drug for diagnosis, treatment, mitigation or prevention of any life-threatening disease or any disease requiring therapy for unmet medical need.

Update on Drugs and Vaccine – COVID-19

Dr Deven Parmar, Chairman, Medical Committee informed that clinicaltrials.gov provided a detailed view of all clinical studies being conducted on COVID-19. There are 2984 studies by 113 countries in progress and in India there are 30 studies being carried out at 70 locations. Also there are 190 COVID-19 vaccine candidates being studied and India has three vaccines that are in advanced stage of Clinical Trials. He explained citing cases about the NIH Guidelines defining a COVID-19 Severity Spectrum that include asymptomatic or presymptomatic infection, mild illness, moderate illness, severe illness, critical illness etc. Referring to the Guidelines issued by Ministry of Health and Family Welfare on Clinical Management Protocol of COVID-19, he explained in detail about medical management of mild, moderate and severe Coronavirus disease. He explained about the Convalescent Plasma and Remdesivir therapies which hospitals in Mumbai and Delhi were already using. Dr Parmar also replied to queries raised by Members and informed that there were

about 65 studies being conducted on HCQ globally and early use of Hydroxychloroquine (HCQ) had shown 75% improvement which was very good. He also informed that Zydus had successfully completed Phase I Clinical trials of a vaccine for COVID-19.

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IDMA-Aptar Webinar on Ocular Drug Delivery

IDMA and Aptar Pharma had jointly organised a Webinar on "Ocular Drug Delivery; A Therapeutic Area with an Interesting Past and a Fascinating Future" on 5th November 2020. The Webinar was well-attended with over 92 participants from about 54 pharmaceutical manufacturing companies, mostly senior management level, involved in manufacturing and marketing of ophthalmic products and solutions. There were three subject expert speakers from Aptar Pharma, Germany, who spoke about different aspects of ocular drug delivery. Dr Deven Parmar, Chairman, IDMA Medical Committee moderated the QA session. A report would be published in IDMA Bulletin for information of Members.

REPORT OF MEMBERSHIP COMMITTEE

This Year the Membership at the year-end stood at 1077. It was a year when the pharma industry was facing a lot of hardships and getting accustomed to the Covid-19 Pandemic. Yet, we were involved in bringing more Members to the IDMA fold so that they benefit by the activities of the Association. During the year, **35 New Members** were inducted namely, **20 Principal Members**, **12 Associate Company Members**, **2 Corporate Member** and **1 Associate Academic Member**, increasing the Membership to 1077.

Due to financial problems faced by our members in the current situation, 477 Members have not renewed their Membership despite repeated follow-ups. As a very special case, we have decided to give these members another chance to renew their membership during the FY 2021-22. The IDMA Membership strength is currently 1077 Members.

REPORT OF MSME COMMITTEE

Interest Equalisation Scheme (IES) for MSMEs for Pre and Post Shipment credit

National President informed that, as per the FTP 2015-2020, initial Interest Equalisation of 3% was increased to 5% with effect from 2nd November 2018 in respect of exports by the MSMEs and was to be availed by MSMEs till the term of FTP policy. DGFT had already extended the FTP term for one year till 2021, but RBI had not notified the banks on the same. In absence of RBI circular for extension of the Interest Equalisation Scheme (IES) to the banks, MSMEs were being charged full interest rate by banks @ PLR and no benefit was being passed on to the MSMEs as was prescribed in the Trade Notice No. 45/2018-19 dated 1st February 2019. We made a submission to Finance Secretary on 10 April 2020 to recommend to RBI to immediately issue circular for extension of IES.

Validity of Interest subvention for MSMEs extended

National President informed that, in order to further provide interest relief of 2% to MSMEs, RBI informed on 7 October that Government of India had extended the validity of the Interest Subvention Scheme for MSMEs till March 31, 2021. Also, fresh or incremental term loan/working capital limit extended by co-operative banks from March 3, 2020 has been made eligible for coverage under the Scheme

Need to categorise Pharma MSMEs as Labour Intensive

Members discussed that pharma MSMEs were losing out on incentives and support from Government as they were being clubbed with all other MSMEs. Pharma Industry was labour intensive and provided employment to lakhs of people and hence required to be provided special benefits. Also there was a number of regulatory requirements which had to be met by all manufacturers. Pricing of pharma products was controlled directly under DPCO both for Scheduled and Non-scheduled drugs. Schemes such as CLCSS were introduced to support upgradation of machinery and tools for SSI units on a common platform for all industries which were not successful as it did not take into account the special requirements of pharma regulations. National President suggested that a representation may be prepared on this issue.

MSME further redefined to support Manufacturers

National President informed that, for the last few years we had been requesting Government to review the outdated categorisation of Micro, Small and Medium Enterprises, and revise it to reflect the present day requirements. The Hon'ble Finance Minister Mrs Nirmala Sitharaman had revised the definitions of MSME on 13 May 2020 to include investment and turnover, as discussed in the last Executive Committee meeting. However, under this revised definition, even medium scale units covered investment only upto Rs. 20 crores and turnover upto Rs. 100 crores. As this was inadequate for setting up a pharma manufacturing unit or for growth of existing units, we requested Government to increase the turnover limits to provide better growth-friendly incentives

to MSMEs. On 1st June 2020, Ministry of MSME issued a notification [G.S.R. 1702] revising the definitions further to restrict it to manufacturing units only covering investments in Plant and Machinery or Equipment, as: (1) micro enterprise redefined as investment upto Rs. 1 crore and turnover upto Rs. 5 crores, (2) SSI investment upto Rs. 10 crores and turnover upto Rs. 50 Crores and (3) medium enterprise with investment upto Rs. 50 crore rupees and turnover upto Rs. 250 crores. Government also informed that exports will not be counted in turnover for any enterprise whether micro, small or medium.

Mr S R Vaidya, Chairman, MSME Committee informed that the issue was mainly in implementation and disbursement of loans. Under the Finance Minister's package, special soft loans were to be provided to MSMEs under the condition that 20% of loan amount availed during the previous financial year would be provided at 7.5% interest p.a. irrespective of the loan amount sanctioned. Members discussed that MSMEs could not benefit from the schemes earlier as the nodal bank SIDBI had very limiting conditions and were averse top release the loans in time. Members were informed that the Association had recommended that all banks be allowed to participate in these special schemes. The Reserve bank of India was now monitoring all banks, with banks required to provide statements of loan disbursals every week to RBI.

Mr S R Vaidya, Chairman, MSME Committee informed that their Committee has supported IDMA Secretariat to raise revenues through advertisements in IDMA Bulletin, Seminars & Webinars Sponsorships courtesy of M/s. Aptar Pharma with tactical support from IDMA Secretariat.

REPORT OF NDPS COMMITTEE

IDMA Challenge to NDPS notification in Supreme Court

Mr M Devesh, Chairman, NDPS Committee informed that a notification in 2009 had specified that the quantity of any NDPS determined for penal action would be the total weight of the formulation seized and not the actual or pure content of the NDPS that was contained in the formulation. This meant that if any specified NDPS drug is in combination with any other non NDPS drug or with any other material (such as excipients), the aggregate weight would be considered to determine its classification as small quantity or commercial quantity. The penal provisions include 1 year imprisonment and/or fine for small quantity, and for commercial quantity, imprisonment of 10 years to 20 years and a fine. We filed an intervention application in Supreme Court on this matter. The matter was heard in the recent past under the bench headed by Chief Justice Gogoi but the bench was re-constituted due to retirement of one of the Judges. The matter came up again for hearing on 19 February 2020 in front of a 3 bench Judge headed by Shri Arun Mishra. Our Senior Counsel Mr. Anand Grover argued on the same.

The Judgement was delivered on 22 April 2020 which was not in favour of IDMA. We lost the challenge, as the Supreme Court held that the quantity of neutral substances in a mixture containing

narcotic drugs or psychotropic substances must be taken into account along with the actual weight of the offending drug while determining 'small or commercial quantity' for the purposes of penal provisions, under the NDPS Act, 1985. This is not positive for Industry as neutral substances in a dosage form including the packaging weight would be considered (total weight of the dosage form and not just the active ingredient) for the purposes of a punishment under NDPS Act and Rules. Members discussed the matter. National President requested Mr Devesh to seek legal opinion on further course of appeal and action.

Representation of IDMA at the United Nations CND Session, Vienna (March 2 -6th, 2020)

Mr. M Devesh attended the 63rd Session of the Commission on Narcotic Drugs (**CND**) in Vienna, Austria, on 2-6 March 2020, representing IDMA. The United Nations Commission on Narcotic Drugs (CND) was established by Economic and Social Council (ECOSOC) Resolution 9(I) in 1946, to assist the United Nations ECOSOC in supervising the application of the international drug control treaties and is an operational segment for exercising the role as the governing body of UNODC. The CND reviews and analyzes the global drug situation, considering supply and demand reduction. It takes action through resolutions and decisions. The CND is mandated to decide on the scope of control of substances under the three international drug control conventions (1961, 1971 and 1988 Conventions). The CND has 53 member States (countries) that are elected by ECOSOC and is chaired by a Bureau, including one member per Regional Group.

Processing of NDPS export/import permits during lockdown

Mr M Devesh, Chairman, NDPS Committee informed that IDMA submitted a representation on 27 March 2020 to Narcotics Commissioner, Gwalior (with copy to Director Narcotics) requesting that the process of application of export/import permits during lockdown by Central Government be digitised and route change permitted a 48 hours before the shipment date. As per our request, the process of application of export/import permits was digitised and route change permitted, 48 hours prior to the shipment date. This worked very well and several companies have reported that permits were issued in 8 to 10 days compared to 21 to 30 days earlier. Also the delays due to courier services, physical interaction with CBN officials or loss of permits during transits were eliminated. CBN had issued Public Notices dated April 1st, 2020, July 7th, 2020 and another on August 4th, 2020 permitting submission of scanned copy of the application along with self-authenticated copies of all documents. The facilitations allowed were temporary measures applicable only till August 30th, 2020.

A submission to Department of Revenue, Ministry of Finance to digitise the process of import/export permits was made on May 8th, 2020 – to accept scanned copies of applications for export authorization/import licence/NOC, import and export permits, and issue relevant permits and NOCs by email or upload the same on Customs portal and permit route change by prior

intimation to CBN, atleast 48 hours prior to a shipment. A representation to this effect was also made to Ministry of Commerce and Department of Pharmaceuticals. A further representation was made to **Hon'ble Shri. Anurag Singh Thakur,** Minister of State for Finance & Corporate Affairs, on December 22nd, 2020. The same is still under consideration by Department of Revenue, Ministry of Finance.

A representation to NCB was also submitted to grant time to file the Quarterly returns for January - March' 2020 quarter, by April 30th, 2020, for Schedule A substances, as prescribed under sub-clause 6) and 7), of clause 4) of the RCS Order, 2013. NCB had considered the same and granted extension till May 31st, 2020.

CDSCO Meeting with stakeholders for discussion on formulation of guidelines for labelling of performance enhancing drugs (Doping drugs) on 23.06.2020

The following persons attended the same:

1. Mr. M. Devesh, Chairman – NDPS Committee
2. Mr. Ashok K Madan, Executive Director

Regarding disposal of NDPS Products

Mr Devesh informed that disposal of Narcotic substances – Manufactured drug and Essential Narcotic Drug is as provided under Rule 45-A of the NDPS Rules and an application is required to be made to the Narcotics Commissioner in the prescribed format.

In case of Psychotropic substances, destruction is as stipulated under the Drugs and Cosmetics Act and Rules and there was no need to take separate permission from any other authority.

In case of Controlled substances, application for destruction is made to the Zonal Director, Narcotics Control Board as stipulated in the NDPS (RCS) Order, 2013. Dr George informed that a detailed report on destruction be published in IDMA Bulletin dated 21 September 2020.

Following representations were submitted during the 2020:

1) Representation to Additional Secretary (Revenue) regarding stalling of export NOCs for Psychotropic substances – Rule 58 (2)(b**)** was made on January 7th, 2020.
2) Representation to Joint Secretary (Revenue) seeking clarification as to whether the requirement to obtain URN 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 was made on Feb 23rd, 2021.

REPORT OF NUTRACEUTICALS COMMITTEE

Members raised the issue about FSSAI not recognising:

- Combination of Vitamin C (as 500 mg) + Zinc that was being recommended for boosting immunity.
- Methylcobalamin as a nutraceutical ingredient.

Accordingly a correspondence was forwarded to CEO of FSSAI pertaining to methylcobalamin as an already approved ingredient under the schedule I of vitamins and minerals, including rationalizing its need and justification, as per the stated footnote in the regulations.

Post the same a virtual interaction was facilitated by IDMA with Mr Arun Singhal, CEO, FSSAI on 27 Oct 2020 during the course of its monthly meeting. At the outset, Mr Singhal informed that India's nutraceutical market is about Rs. 30,000 to Rs. 35,000 crores at present and is expected to double to over Rs. 60,000 to Rs. 65,000 crores in the next 10 years. During the interaction, Dr R K Sanghavi, Chairman of Nutraceutical Committee elaborated on specific concerns:

- To include in the Footnote in Schedule 1 words "Active Moieties" in addition to derivatives, salts, esters, chelates, etc.
- To consider substituting the word Recommended Dietary Allowance (RDA) with tolerable Upper Intake Level (UL), or at least 50% of UL, in the FSSA as well as each instance in the regulation for nutraceuticals. FSSAI in its 2020 amendment had accepted adoption of 50% of TUL (Tolerable Upper Limits) as criteria for capping quantities of vitamins and minerals that are incorporated in the FSDU (Food for Special Dietary Use) products under the FSS Regulations 2016 for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food.
- To mention, in addition to being implied in modified footnote, various vitamin derivatives/ pro-vitamins like methylcobalamin, L-methylfolate, benfotiamine, panthenol, pantethine, pyridoxal phosphate, pyridoxal-5-phosphate, L-methylfolate, L-methylfolate calcium and adenosylcobalamin under the Table B of Nutraceutical Schedule-VI as separate entities.
- The alter criteria for new ingredient approval from documented history of safe usage of at least fifteen years in India and thirty years in the country of origin to about four years of global usage.

As per Mr Singhal's suggestions separate notes regarding the desired footnote wordings and inclusion under the nutraceutical Table B of Sch-VI of concerned regulations, was forwarded by Dr Sanghavi. The Chairman is also working on a compilation for justifying the

need, sans any concerns, for permitting the UL for all nutraceuticals, health supplements, and other categories mentioned in the related regulations; the same will be forwarded in due course.

Dr Sanghavi informed that Mr Ashok Madan would need to follow up with FSSAI to ensure that our detailed point by point suggestions made in our submission are considered while finalizing the notification. National President requested Mr Madan to follow up with CEO, FSSAI on this matter. Also Mr Madan also informed that FSSAI has decided to make policy amendments twice a year, in January and in June.

In another first, FSSAI has collaborated with AYUSH in setting up a new entity known as AYURVEDA AHAR for approval of traditional healthy Indian food items. After much persuasion and rigorous follow-ups by Dr R K Sanghavi and his associates, FSSAI has ultimately initiated interaction with CDSCO to resolve the issue of deciding on vitamins and minerals supplements. A product with quantities of vitamins / minerals up to specified 1x RDA amounts is to be considered as Health Supplement / Nutraceutical under FSSAI and all others exceeding RDA limits will be considered as "drugs" and need to be certified by the DCG(I).

REPORT OF PRICING / CONSUMER AFFAIRS COMMITTEE

Meetings with DOP, DCG(I), NPPA and DOH

National President informed that on 20 February 2020, he along with Secretary-General Mr Daara Patel and Executive Director, IDMA-Delhi Office Mr Ashok Madan had called on various key officials at Delhi as below and discussed certain key issues as below:

Meeting with Dr. Vaghela, Secretary, DOP:

- On the issue of **supply of APIs and formulations**, Dr. Vaghela clarified that there was no ban. DOP letter to DGFT had only requested to take appropriate caution with regard to restriction on exports. He requested us to write to our members to exercise restraint in exports of APIs as well as formulations for the next one or two months to safeguard our people's health.
- **PTUAS** – He informed that a revised scheme was under consideration and there was a proposal to cover 4500 SME units over a period of 5 years with a corpus of around Rs.3000 Crore.
- **MSME Definition**: Members discussed that the present investment based definition of MSME was outdated, as Rs. 10 crores limit on plant and machinery for Medium scale units was not sufficient for setting up a bulk drug unit. It was discussed that Government had proposed amending the definition to base it on turnover upto Rs. 75 crores for SSI and Rs. 250 crores for Medium scale units. However due to certain objections raised by Laghu Udyog Bharati,

the proposal was kept in abeyance. Members discussed that Mr Rajesh Gupta, an active Member of Laghu Udyog Bharati could be requested to take up the matter with Government proposing turnover based amendment for pharma SMEs.

- **UCPMP** – The Secretary advised all Associations to be more pro-active with updated Ethics and Apex Committees on their websites. We had informed him that IDMA had already set up Ethics and Apex Committees in year 2017. Regular reporting to DOP was also requested by the Secretary.
- On the issue of **Trade Margin Rationalisation** (TMR), the Secretary informed that as per the data available with the Government, 40% of the products available in the country had Trade Margins of around 2000%. We pointed out that this particular type of channel was referred to as "Propaganda basis" and is not promoted through Doctors & MRs and the Trade Margin may hence be higher. However, this market was only around 5 to 7% of the total Indian market. Secretary requested us to find ways and means to identify/categorise these types of products.

Meeting with Mrs. Shubhra Singh, Chairperson, NPPA:

- **Implementation of price from retrospective batches** - NPPA Chairperson opined that this was an old topic and still hanging on. She queried that when GST could be implemented the very next day, then what was the problem in implementing the price in case of medicines. However, she further said that in case of proposed changes which are likely to come, this issue may become redundant.

National President informed that they also made courtesy calls on **Mrs. Ritu Dhillon, Member Secretary, NPPA** and **Dr.Mandeep K Bhandari, Joint Secretary, Health.**

NPPA notifies CP based on Institutional data

National President informed that NPPA worked out Ceiling Price of five Scheduled formulations [Calcium Carbamate 500mg tablet, Ferrous salt 100mg + Folic Acid 500 mg tablet, All-trans Retinoic Acid 10 mg capsule, Daunarubicin 5mg/ml injection (20 mg pack) and Ethyl Alcohol (denatured) 70% Solution] on 19-2-2020 based on institutional data and requested for representation within 10 days. Members discussed that we need to be careful that NPPA does not make notifying prices based on institutional and hospital a routine practice. Dr Amit Rangnekar, Chairman, Pricing /Consumer Affairs Committee informed that the draft working was uploaded on NPPA website and we informed all Members by email on 25 February 2020. NPPA had been seeking data from manufacturers for the last 2 years on these products. We have published the NPPA circulars in IDMA Bulletin as well as emailed the request to all Members to submit the data, as available. As NPPA had not received data and had to mandatorily fix prices as per DPCO 2013, they had already notified the Ceiling Prices earlier based on institutional data. However, as the prices notified did not provide for Retailer's margin, IPA and CII had

represented to NPPA to revise the prices. Hence they have now notified Ceiling Prices with the Retailer's margin.

DOP Committee formed

National President informed that DOP had set up a Committee headed by Dr P D Vaghela, Secretary, DOP on 11 March 2020 which was co-ordinated by Shri Navdeep Rinwa, Jt Secretary. Dr Vaghela held regular Video Conferences to discuss issues in manufacturing and distribution of pharmaceuticals. Mr Rinwa was co-ordinating with us on a day-to-day basis, and at times many times in a day. As Members kept informing us about various issues, we kept the Committee updated on the issues such as difficulties in getting permits from local authorities for manufacturing units, slow functioning of ports in Mumbai and Chennai etc. DOP gave directions to the concerned States and Departments to address the problems for quick resolution.

DPCO Reform – submissions

Members discussed that the Minister of State for Chemicals & Fertilisers Shri Mansukhlal Mandaviya was taking up DPCO reforms. Dr Amit Rangnekar, Chairman, Pricing/Consumer Affairs Committee informed that IDMA had provided suggestions earlier which were still valid. Our main recommendations were (1) Price revision from next batch; (2) In case of increase in API costs, to allow price revision based on a formula suggested by industry experts.

IDMA Submission on NPPA draft Guidelines for discontinuation of scheduled formulations

Dr Amit Rangnekar, Chairman, Pricing/Consumer Affairs Committee informed that NPPA had issued draft guidelines on 1 June 2020for discontinuation of scheduled formulations. We made a detailed submission emphasising that the guidelines for discontinuation of scheduled formulation under para 21(2) should not be linked to any other Para of DPCO 2013, namely para 3 and para 19, nor to New Drug under Form-I. When the government policy was to ensure 'ease of doing business', linking unrelated paras of DPCO 2013 created more restrictions and slabs for discontinuation of scheduled formulations, defeating the purpose. The aim of providing such guidelines should be to avoid shortages and the clauses and slabs should ensure gradual discontinuation and no shortages.

He further informed that since DPCO was notified in 2013, there has been a surge in API prices which is disproportionate to the notified ceiling prices based on the WPI which are notified every year. Also, para 13(2) in DPCO 2013, stipulates that if price of the existing manufacturer of a scheduled formulation is lower than the notified ceiling price it has to continue to be maintained at that level except for the annual WPI increase as allowed. Existing manufacturers of scheduled formulations have received a price increase of only around 3% in seven years while the prices of API per kg has risen steeply during the same period. Citing the example of Paracetamol, he informed

that price increase during this period was over 70%in the same period making it almost unviable to continue the scheduled formulation, though companies could not discontinue due to provisions of para 21(2) which entail a public notice and approval for discontinuation under Form IV.

He suggested that on the recommendation of NITI Aayog, NPPA had provided 50% increase in price to certain formulations in December 2019 and we can request NPPA to consider a similar revision now to adjust for the steep increase in API prices. Alternatively, he proposed to make a representation to NPPA to revise para 21 (2) and 13(2) that were restrictive. Para 13(2) would need to be amended to allow less than CP to be raised on par with CP. The system would need to be institutionalised for automatic revision. He also proposed a few slab rates for allowing discontinuation over a specified period under para 21(2) such as, for products upto 1%MAT share, manufacturing to be continued for only 30 days, for MAT share 1% to 5% to continue production for 3 months, 5% to 10% for 6 months, 10% to 25% for 9 months and over 25% for 12 months etc. Members agreed to the representation to be made, but it was suggested that only 1 or 2 rates may be proposed without complicating the issue.

Consumer Protection Act 2019 in force from 20 July 2020

National President informed that the newly enacted Consumer Protection Act 2019 came into force from 20 July 2020, replacing more than three decades old Consumer Protection Act, 1986. The Act sought to overhaul the process of administration and settlement of consumer disputes, with strict penalties, including jail term for adulteration and misleading ads by firms. It proposed setting up of a Central Consumer Protection Authority (CCPA) to promote, protect and enforce the rights of consumers as a class and prevent loss arising from unfair trade practices. CCPA can also initiate class action, including enforcing recall, refund and return of products. There was provision for mediation and e-filing of cases and consumers could file complaints from anywhere and do not need to hire lawyer to represent their cases. An exclusive law dealing with Product Liability has been incorporated and a manufacturer or product service provider or product seller would be responsible to compensate for injury or damage caused by defective product or deficiency in services.

Stakeholders National Consultation Meeting on NLEM

The Stakeholders National Consultation Meeting (SNCM) for revision of NLEM 2015 was held as VC on 17th August 2020. Dr Amit Rangnekar, Chairman, Pricing/ Consumer Affairs Committee, Dr Kiran Marthak, Vice-Chairman, Medical Committee and Mr Ashok Madan had represented IDMA. He requested Dr Rangnekar to brief Members. Dr Rangnekar informed that Dr Y K Gupta, Vice-Chairman of the NLEM Committee had chaired the meeting. We raised our issues about certain matters and other Associations also raised other issues. They replied to the queries as below:

- Essentiality as the sole criterion for inclusion in NLEM. They informed that NLEM will be only on essentiality, where large sections of population are involved.
- On the request again for restricting span of control of NLEM to specific strengths and dosages, they informed that they will convene a separate meeting to discuss on the strength and rationality as basis for inclusion in NLEM.
- To our request for postponing NLEM to the second half of 2021 due to the ongoing COVID-19 pandemic, they agreed in principle and will inform SNCM to consider the request.
- It appeared that certain formulations listed in NLEM are apparently not approved by DCG(I) and the Committee was requested to ensure that only DCG(I) approved medicines are included in NLEM. Members discussed the matter and it was decided that we should not insist on this as it could impact our MSME Members.
- On the request that since SR drugs are not specified in NLEM, hence are not considered as separate price category under DPCO and clubbed with conventional drugs, they have agreed to inform the Committee.

Members discussed that High Courts have ruled that innovative drugs such as SR, CR etc should not be linked with ordinary dosage forms while fixing prices. NLEM 2015 has also specified that price fixation for such formulations must be independently done and not clubbed with ordinary dosages listed in DPCO.

NPPA issues revised Guidelines for discontinuation of Scheduled formulation

Dr Rangnekar informed that NPPA had issued revised Guidelines dated 14 August 2020 for discontinuation of scheduled formulations under DPCO. We had made a detailed submission and some suggestions were accepted. Now only two slabs of applicants are recognised. If an applicant with <1% MAT wanted to discontinue, he would need to apply in Form IV and issue public notice in one newspaper. If an applicant with >1% MAT wanted to discontinue, then he has to apply in Form IV and within 60 days applicant will have to place advertisement in two national dailies. NPPA may ask the applicant to continue production for next 12 months and then discontinue. Members discussed that with the COVID-19 pandemic, companies were struggling to meet regular expenses and releasing advertisements in national dailies was unnecessary and an additional financial burden. We need to request that the requirement of releasing advertisements must be removed. After discussion, National President requested Dr Rangnekar to prepare a representation to NPPA not to insist on <1% MAT applicants at least to advertise in one national newspaper.

Another requirement was that a company wishing to manufacture or market a new FDC with a scheduled drug, would need to seek approval from NPPA. Members discussed that in India FDCs are preferred and one has to keep introducing such combinations. The Company should be allowed to seek approval from NPPA for such new drugs in Form I. If scheduled formulation is discontinued with proper approval and combination launched as per market needs, it should not

be termed as evasion. Again for >MAT 1%, average production per quarter has to be maintained for next 3-4 quarters for products to be discontinued. Members discussed that it would be difficult to do so due to the COVID-19 pandemic and related lockdowns and restrictions. He informed that NPPA has accepted some of our suggestions such as uploading of Form 4 applications for discontinuation on NPPA website and not linking other paras such as para 3 (API price), para 19 (Extraordinary circumstances) to Form I (New Drugs) under DPCO.

Eco System for timely disposal and monitoring of applications filed with NPPA

Dr Rangnekar informed that NPPA had issued a circular informing that they are working on a fully automated Eco System for timely attending to online applications filed under various Forms I,II,III,IV,V of DPCO, 2013. NPPA has also provided a checklist for filing Form I. Timelines have been prescribed for disposal of applications under various Forms. For Form I and Form IV, NPPA will reply within 60 days. For Form II for submission of revised-prices for scheduled Formulations, for Form III for Quarterly API sale, production etc and Form V for Price List, manufacturer needs to update on IPDMS within 15 days of the notification. Members discussed that many SME Members were still not fully conversant with DPCO provisions and a Webinar may be organised to update and educate them. It was discussed that a small fee could be charged for this Webinar. Dr Rangnekar informed that he along with Vice-Chairman Mr C V Venkataraman will organise this Webinar. Interested Members may be requested to send in their queries so that they could address them during the Webinar.

Second Meeting of DOP Pharma Associations

Dr Viranchi Shah informed that the Second DOP Pharma Associations meeting was held on the same day (21 August) thru' VC and was chaired by Dr P D Vaghela, Secretary, DOP. OPPI, IPA, CII, FICCI etc were also represented. A number of issues were discussed. We raised the issues of Trade Margin Rationalisation, NLEM revision, Price Control to be applicable to specific strengths as in NLEM, Implementation of price from Prospective batch, PTUAS, Environment Approvals and many other issues. Other Associations also raised issues. After discussion, the DOP Secretary sought the following:

- Representation from the Associations to DOP on prioritised APIs that can be produced in the same plant so that no major additional investment would be required.
- Associations were advised to submit representation requesting for extension of date of Environment notification inviting applications upto 30th September 2020, extension of B2 category applications and to add KSMs and intermediates along with APIs in the list.
- Ms Remya Prabha DD, DOP was requested to write a letter to all associations with reference to the Fall Clause issue.

The DOP Secretary informed that QR Code would be implemented eventually. There would be only one system of authentication. A new committee in Ministry of Health under the Jt Secretary

would handle this matter. He also informed that DOP is working on R&D policy and had formed a Committee to give recommendations to restore R&D Weighted Deduction of 200%.

Meeting with Ms Aparna, IAS, DOP Secretary

IDMA had a virtual interactive meeting on 3 October 2020 with Ms S Aparna, IAS, the new Secretary of Department of Pharmaceuticals. The Secretary was keen to first talk to IDMA and hence the meeting was organised at a very short notice. National President was joined by Past Presidents, Secretary – General, various Committee Chairmen and over 30 EC Members in the meeting. We informed the Secretary about a few urgent and pending issues such as Track & Trace System, Fall Clause, FDCs, revision of Schedule M, GST, Pricing, Environmental issues, PLI Scheme etc. We thanked DOP for their initiative in launching the PLI Scheme. The Secretary appeared to have taken note of the developments and appreciated the dynamism of her predecessor Dr P D Vaghela and gave all the credit to him. She promised her support in all matters and agreed to interact regularly with us in future too to address issues.

Felicitation of Dr. P.D. Vaghela, IAS

National President informed that, earlier on 29th September 2020, all the Associations representing Pharmaceuticals and Medical Devices held a VC meeting with Dr. P.D. Vaghela, Secretary, DOP and felicitated him on his superannuation. We thanked him for his various initiatives in support of industry during COVID-19 pandemic, specially during the early days of lockdown period, and also his continued support during his tenure. Mr. Ashok Madan attended the meeting in person and presented a Souvenir to Dr Vaghela on behalf of IDMA and other Associations. Dr Vaghela later took charge as Chairman of TRAI.

Meeting with Mr. Rajneesh Tingal, Jt. Secretary, DOP

National President informed that Mr Ashok Madan had a meeting with Mr. Rajneesh Tingal, Joint Secretary DOP on 7 December. He requested Mr Madan to brief Members. Mr Madan informed that Mr Tingal had recently been directed to handle work pertaining to DPCO and Pricing. As Mr Tingal informed that he had yet to make a detailed study of the issues, he briefly talked to Mr Tingal about our concerns on proposed NLEM, prospective implementation of revised price, Span of control, Surge in API prices, Para 13(2) of DPCO, Incremental innovations, Non-application of provisions etc. He thanked Dr. Amit Rangnekar, Chairman, Pricing/Consumer Affairs Committee and Mr. S. V. Veeramani, Past President for providing these key points for discussion.

REPORT OF PUBLICATIONS COMMITTEE

IDMA Bulletin and Indian Drugs digital versions

Dr George Patani, Chairman, Publications informed that due to the nationwide lockdown, printing presses were not allowed to run, as they are not considered essential services. Hence we

could not print our weekly publication IDMA Bulletin and monthly Indian Drugs. He acknowledged the efforts of Mr. Daara Patel, Mr T R Gopalakrishnan, Mr Melvin Rodrigues, Mr CKS Chettiar and Mr Ajay Singh in managing to prepare digital issues of these publications. The digital copies of IDMA Bulletin & Indian Drugs are being emailed to all Members and also uploaded on IDMA website.

National President informed that even during the lockdown period the IDMA Bulletin was being published regularly every week and released digitally to all Members. He congratulated Dr George Patani, Chairman, Publications Committee, Dr G G Nair, Editor and IDMA Secretariat. Members appreciated the same and it was discussed that the digital reached them on time and much earlier than the print copies mailed through the Post Office.

Dr Gopakumar Nair, Editor IDMA Bulletin informed that he was very pleased to note that IDMA Bulletin continues to be published regularly every week, though as a digital publication, even in these difficult times. He thanked the IDMA Secretariat for their commitment and excellent work.

REPORT FOR REGULATORY AFFAIRS COMMITTEE

Meetings with DOP, DCG(I), NPPA and DOH

National President informed that on 20 February 2020, he along with Secretary-General, Mr Daara Patel and Executive Director, Delhi Office, Mr Ashok Madan had called on various key officials at Delhi as below and discussed certain key issues as below:

Meeting with Dr. V.G. Somani, DCG(I):

- Dr Somani informed us that the **R&D Committee** that was earlier functioning from Department of Health Research has been formed within the CDSCO office to make things easier for the industry.
- DCG(I) had issued a circular extending timeline for submission of **data for Category 'd' FDCs** up to 30 May 2020. Kokate Committee as well as Ministry of Health had earlier deleted the molecules where Phase IV was not feasible. He informed that PSURs cannot be equated with or replace Phase III and Phase IV trials. DCG(I) had also issued another notice dated 20 Feb 2020 to extend timeline for submission of data on 49 FDCs + 19 FDCs in the 294 FDCs category. Members discussed that the cost of conducting Phase IV trials would be prohibitive for SMEs. National President informed that DCG(I) had suggested that companies could come together to conduct the Phase IV trial to establish safety. With regard to Phase IV trials, DCG(I) had advised us to submit a representation giving our suggestions.
- **Schedule M** – We informed Dr Somani that we had submitted a detailed representation on the proposed revisions on 17 January 2019 which highlighted the regulatory and legal implications of stipulating Guidelines as Rules and also provided point-wise suggestions on the proposed revision. DCG(I) requested that a specific letter may be submitted clearly stating

that WHO Guidelines should only be for guidance purpose and making them mandatory could lead to complications and criminal prosecutions. National President requested Mr S M Mudda, Chairman, Regulatory Affairs Committee to prepare the representation.

- **SUGAM portal** – DCG(I) requested us to send 4 or 5 industry experts to meet him and in turn they would be put in contact with CDAC (Centre for Development of Advanced Computing) to finalise and fix issues in SUGAM portal. Secretary-General informed that we have identified and forwarded details of four experts who are hands-on in uploading data on SUGAM portal and the related issues.

National President informed that they also made courtesy calls on **Mrs. Ritu Dhillon, Member Secretary, NPPA** and **Dr. Mandeep K Bhandari, Joint Secretary (Health).**

CDSCO Workshop at Mumbai on 3 February 2020

Secretary-General informed that as desired by Dr V G Somani, DCG(I) IDMA had organised the 'Workshop on E-Governance Initiatives of CDSCO' on Monday, 3rd February 2020 at Sunville, Worli, Mumbai jointly with CDSCO and CDAC. The Workshop was a huge success with participation of over 375 delegates and 75 officials from CDSCO and FDAs of Maharashtra, Madhya Pradesh, Goa, Uttarakhand etc.

'Marketer' defined under D&C Rules

National President informed that the Ministry of Health and Family Welfare issued notification (G.S.R. 101 dated 11 February 2020) to define 'Marketer' under Drugs and Cosmetics Rules to be effective from 1st March 2021. Under this Rule, the Marketer would be held responsible for ensuring quality and regulatory compliances of the marketed drug. However, this would apply only when the Marketer's name was printed on the label along with the manufacturer's and the Marketer may not be held liable if his name was not included in the label. Mr S M Mudda, Chairman, Regulatory Affairs Committee informed that we had made a detailed submission on 24 July 2019 highlighting the legal aspects and impact on cost and availability of drugs. We suggested that the responsibility for quality and regulatory compliance cannot be placed on the marketer grossly and had to be specified clearly. Also the definition of 'Marketer' as notified would need to be modified to remove the words 'agent', as the Marketer worked on a P-to-P contract basis.

(a) Responsibilities of Marketer

Mr Mudda informed that the responsibilities of Marketer for quality and regulatory compliance was notified vide G.S.R. 101 dated 11 February 2020. The Rule comes into effect on 1 March 2021. We had made a detailed submission on the draft notification issued last year highlighting the legal and regulatory compliance issues that would arise. However, the draft notification has been finalized without considering our suggestions. We have now made a submission dated 23 September 2020- pointing out the various issues in implementing the Rule as under Section

19 (3), the Act provided relief to any person, not being the manufacturer of the drug or his agent from being liable for a contravention of manufacturing Rules. We have made suggestions on how to resolve the matter by revising the definition of Marketer, introducing a new section in D&C Rules, adopting the concept of Contract Giver and Contract Acceptor from EU GMP etc.

Validity of Registration Certificates & Form-10 of API and formulations

National President informed that we made a submission to DCG(I) on 23 April 2020 to grant 6-month extension in validity of Registration Certificates & Import Licenses in Form-10 which had expired in the recent months since January, 2020 and also those which were expiring in April & May 2020 for both APIs and Formulations. The extension would be announced very soon.

Ministry of Health constitutes High-level panel to reform drug regulatory system

National President informed that the Ministry of Health and Family Welfare constituted a high-level Committee as an urgent measure to reform the drug regulatory system in India and to simplify and expedite the drug approval process, as India continues to fight the Covid-19 pandemic. Mr Adar Poonawalla, CEO of Serum Institute of India, and Zydus Cadila's Mr Pankaj Patel, along with top officials from the DOP, ICMR, DBT and AIIMS constitute the Committee chaired by Shri Rajesh Bhushan, IAS, Officer on Special Duty, Ministry of Health, while Joint Drug Controller of India Dr Eswara Reddy will assist the Committee. The Committee will work on adopting global standards for drug and medical device regulation amid the ongoing pandemic.

CDSCO Regulatory Streaming and Initiatives

National President informed that Dr V G Somani took a number of initiatives for fast track approval of COVID-19 related proposals. Some of them have been in quick response to industry representations while others have been proactive. A few of the initiatives were as below:

- Validity of all **WHO GMP/COPP** licenses expiring from March to August 2020 were extended by another 6 months from the date of expiry of the certificate (Notice dated 1 May 2020)
- **Import of drugs having residual shelf life of less than 60% allowed**, after taking undertaking from the importer that the drug would be utilised/ consumed before expiry date and no part of the drug would be available for sale and distribution after its expiry (Circular dated 17-04-2020)
- **Validity of BA/BE study centres** which had already applied or would be applying for renewal of Registration within 90 days prior to the date of expiry of its existing registration along with requisite fees and necessary documents were extended till further Orders. (Circular dated 30.04.2020)

New Drugs and Clinical Trials (Amendment) Rules, 2020

National President informed that the Ministry of Health and Family Welfare issued a draft gazette notification [G.S.R. 354 dated 5 June 2020] proposing amendments to the New Drugs and Clinical Trials Rules, 2019. The amendment proposes to allow manufacturing, import etc of any new unapproved drug for Compassionate use even when the drug is not approved for marketing in India. A medical officer of a hospital or any medical institution can recommend a drug for diagnosis, treatment, mitigation or prevention of any life-threatening disease or any disease requiring therapy for unmet medical need.

CDSCO meeting with stakeholders on formulation of guidelines for labelling of performance enhancing drugs

Mr M Devesh, Chairman, NDPS Committee informed that CDSCO had organised a webinar meeting with stakeholders on 23 June 2020 to discuss formulation of guidelines for labelling of performance enhancing drugs. He represented IDMA at the meeting. He informed that these drugs, also referred to as Doping Drugs are published by World Anti-Doping Agency (WADA) and National Anti-Doping Agency (NADA) on NADA website. NADA and various sports bodies in India such as Indian Olympic Association, BCCI, etc undertake extensive awareness programs with sports persons on these prohibited drugs.

At the meeting, he informed them that changing the labelling requirements for performance drugs was not required as all such drugs, barring illegal substances were prescription only drugs, either in Schedule H, H1 or X or NDPS (where in the labelling requirement is NRx). Hence, the question of awareness to general public such as parents, teachers, students, sports persons etc did not arise. Adequate information on the label to state that “for prescription only” was already being printed as notified recently. He was requested by CDSCO to submit a representation on the same, which was done immediately afterwards.

Guide for Dual Use Application at SUGAM Portal

National President informed that Dr Rubina Bose, Deputy DC(I), WZ had provided a Step-by-Step Instructions Guide for filing online for grant of permission for Drugs imported in bulk for Non-Medicinal Use as per Rule 43 of Drugs and Cosmetics Rules 1945. It was published in IDMA Bulletin dated 30 July 2020 for information of Members.

Proposed Revision of Schedule M

Mr S M Mudda, Chairman, Regulatory Affairs Committee informed that the Ministry of Health and Family Welfare had organised a Consultation Video Conference with stakeholders on 16 July for finalising the draft Rules for proposed revision of Schedule M [GSR 999(E) dated 5 October 2018]. He had represented IDMA along with Vice-Chairman Mr S W Deshpande. Mr Ashok Madan had attended in person and handed over a copy of our detailed submission made on 17

January 2019. We reiterated our submission that GMP compliance through the proposed revision of Schedule M needs to be redrafted in line with global practices. This could be framed with minimal Rules and detailed Guidelines to encourage objectivity in compliance. The requirements of GMP are dynamic and details need to be updated in line with developments and concepts evolving globally. The present proposal of enforcement approach was not very conducive for the better compliance of GMP requirements. The Guidelines thus laid down would not have force of law but would be the requirements of maintaining the license and encourage compliance by all the sectors since the fear of regulatory action is removed. We informed that otherwise even minor violations and unintentional errors would be penalised and would require legal resolution every time. The Guidelines could be updated regularly by a Working Committee to be formed for each major GMP subject under the authority of the DCG(I).

FDCs of Vitamins, Minerals etc approved by Kokate Committee

National President informed that CDSCO had approved 471 FDCs of vitamin, mineral and micronutrients, which were declared as rational by Prof. Kokate Committee. He requested Mr S M Mudda to brief Members. Mr Mudda informed that for grant of product licences by the SLAs, applicants have been directed to submit the requisite fees preferably through Bharatkosh for each FDC to CDSCO and then submit the application to the concerned SLA for grant of product licence giving details of the FDC, serial number in the list, stability studies data (6 months accelerated), test specification, method of analysis etc. Every manufacturer permitted to manufacture these FDCs is required to submit Periodic Safety Update Report (PSUR) to DCG(I) as per the New Drugs and Clinical Trial Rules 2019 notified on 19 March 2019, and not submitting the PSUR is considered as contravention of these Rules. As per DCG(I) circular in December last year, MSMEs are required to pay half of the Rs. 2 lakh fees for a FDC declared rational by Prof Kokate Committee and approved by DCG(I). He informed that a representation would be made to DCG(I) requesting that, as these are Vitamin based FDCs, there was no need for PSUR. Also these FDCs should be allowed to be formalised and approved with fees at Rs 15,000 as allowed prior to the NDCT Rules,

FDCs –representation on PSUR

National President requested Mr S M Mudda, Chairman, Regulatory Affairs Committee to brief Members. Mr Mudda informed that the DCG(I) had been notifying SLA approved FDCs considered rational by Kokate Committee in instalments from the year 2016. A procedure was also laid down that Rs. 15,000 fees was to be paid and stability data to be submitted to State FDAs for licence. After grant of licence by SLA, PSUR study was required to be conducted for 4 years on the marketed FDC. Last month, 471 FDCs of vitamins, minerals etc were notified. Now the DCG(I) is reportedly directing all applicants to conduct PSUR study as per the New Drugs and Clinical Trials Rules notified in March 2019, which requires far more detailed study on these already marketed FDCs as long as they are being marketed. We are working on a submission toDCG(I) to revert back to old Rules for PSUR for these FDCs which were being marketed for a number of years.

Pathway to regularise Kokate Committee approved FDCs

Mr S M Mudda informed that the DCG(I) had been notifying SLA approved FDCs considered rational by Kokate Committee in instalments from the year 2016, and since 2018, DCG(I) has notified the list of rational SLA Approved drugs covering 1681 FDCs and 450 FDCs. On 3 August 2020, DCG(I) issued a circular releasing 471 FDCs relating to Vitamins, Minerals and Micro-nutrients approved by Prof Kokate Committee and informed that the applicants were required to comply with the PSUR requirements as per the new NDCT Rules 2019. All the Circulars issued earlier described the pathway and provided instructions for payment of Rs. 15,000 as the fees and for filing the PSUR in accordance with the provisions of Schedule Y. The requirements for PSUR filing was also specified similarly in the NOCs issued by the DCG(I) office to individual companies who had submitted the safety and efficacy data for these FDCs. These drugs reviewed under 18 months policy were already marketed for several years and were not considered as 'New Drugs', and NOCs and not Form 46 were issued to the companies for these products after the FDCs were declared as rational by the Committee. The PSUR reviewers at the DCG(I) office are now directing manufacturers of such earlier approved FDCs to submit, midway, the PSUR data in accordance with the provisions of the new NDCT Rules 2019. This requirement has created a typical situation where the companies, who had already filed the PSUR for the last 2 years as per Schedule Y, are now required to comply with the new NDCT Rules.

We have made a submission to DCG(I) on 19 October 2020 requesting to notify a uniform policy applicable to all manufactures who were issued NOCs for these FDCs under the 18-month policy and for all the subsequent applicants. We have also requested DCG(I) to issue a clarification that the pathway prescribed in the DCG(I) circular dated 12th December 2018 will be followed for all the FDCs cleared in this route and as specified in the circular, fees of Rs. 15,000 will be charged and PSURs will need to be filed in accordance with Schedule Y, as also specified in the individual NOCs. He informed that, as requested by Members, a VC meeting can be organised with DCG(I) to discuss and resolve the issue.

Mr S M Mudda, Chairman, Regulatory Affairs Committee informed that following our detailed submissions on proposed revision of Schedule M and issues in submission of PSUR, he requested that a meeting may be organised with Dr V G Somani, DCG(I) to brief him in detail about the issues. Members suggested that a Webinar may also be organised to discuss about impending inclusion of 'Marketer' under Drugs and Cosmetics Rules from 1 March 2021. Mr Mudda informed that Mr S W Deshpande can be requested to be the expert speaker.

Form 10 license validity to be extended

Members discussed that Ministry of Health and Family Welfare had issued a notification [G.S.R. 2450(E) dated 27 July 2020] extending validity of Registration Certificate issued under Form 41 for 6 months. This was made for ease of doing business in view of the COVID-19

pandemic. However there was no mention of similar extension of validity of Form 10 licence. There are many Members whose Form 10 licenses for import would be expiring in August or September and application had to be made for renewal or fresh licenses which took some time to be issued. It was discussed that a clarification would need to be sought from DCG(I) whether Form 10 licence issued against Form 41 would also be considered similarly valid for 6 months, so that importers will not need to apply again to get Form 10 to avoid duplication of work. National President informed that the Association will submit a representation to DCG(I) shortly on this issue.

Draft Proposal for Import and Manufacture of Drugs for Compassionate use

Mr S M Mudda, Chairman, Regulatory Affairs Committee informed that the Ministry of Health and Family Welfare had issued a draft notification [G.S.R. 354 (E) dated 5 June 2020] proposing to amend New Drugs and Clinical Trials Rules, 2019. The amendment seeks to allow import of unapproved New Drug for Compassionate use for treatment of patients by hospitals and manufacture of New Drug for Compassionate use. The initiatives are welcome. However, the conditions for granting permission is very restrictive, such as quantity for manufacture mentioned is too small and having to seek consent of the patient etc. A meeting was organised on 21 October 2020 to finalise the draft Rules. They had inadvertently failed to inform us of the meeting and we could not discuss these points. He informed that a representation may need to be made to DCG(I) to amend these conditions.

APPQM Series 2

Mr Mudda informed that we have received good response for the Advanced Program in Pharmaceutical Quality Management (APPQM) Series 2. The Program is scheduled to begin from 1 February 2021 and will be conducted virtually. About 25 candidates have registered for the Program. The virtual training program from NSF offers the flexibility of organizing break our sessions like physical break out rooms and encourages team work for problem solving.

Cosmetics Rules

National President informed that the Ministry of Health and family Welfare had recently notified the Cosmetics Rules, 2020 [vide GSR 763 dated 15 December 2020] under the Drugs and Cosmetics Rules. As the entire Cosmetic Rules appears to have been revised, he requested Mr S M Mudda, Chairman, Regulatory Affairs Committee to scrutinize the revised Rules along with his Committee.

AWARDS DISTRIBUTED DURING THE ANNUAL DAY ARE AS FOLLOWS:-

IDMA CORPORATE CITIZEN AWARDS 2019	
Category : Turnover ₹500 Crores & above	**Lupin Human Welfare & Research Foundation**
Category : Turnover Less than ₹500 Crores	**RPG Life Sciences Ltd.**
IDMA QUALITY EXCELLENCE AWARDS - 2019	
Gold Award	**Ind-Swift Limited, Punjab** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*
Gold Award	**Micro Labs Limited, Sikkim** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*
Gold Award	**Blue Cross Laboratories Pvt. Ltd., Goa** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*
Gold Award	**RPG Life Sciences Ltd., Thane** *Category : Bulk Drugs Unit – Companies with Total Annual Turnover Above ₹100 crores*
Silver Award	**Vital Healthcare Pvt. Ltd., Nashik** *Category : Formulations Unit – Companies with Total Annual Turnover upto ₹25 crores*
Silver Award	**Apex Laboratories Pvt. Ltd., Chennai** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*
Silver Award	**Micro Labs Limited, Bangalore** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*
Silver Award	**Pharma Impex Laboratories Pvt. Ltd, Kolkata** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*
Silver Award	**Twenty First Century Pharmaceuticals Ltd., Rourkee** *Category : Formulations Unit – Companies with Total Annual Turnover Above ₹100 crores*

IDMA MARGI MEMORIAL BEST PATENT AWARDS 2018-19	
BEST BIOTECH PATENTS AWARD 2018-19	granted to **M/s BIOCON Ltd.** 33 (18 Patent Families) Patents
BEST PHARMACEUTICAL PATENTS AWARD 2018-19	granted to **M/s Hetero Drugs Limited** 12 API & 5 Formulations Total 19 Patents
BEST API PATENTS AWARD 2018-19	granted to **M/s. Emcure Pharmaceutical Ltd** 13 APIs Patents & 1 NCE Patent (2 Families)
BEST API PROCESS PATENTS AWARD 2018-19	granted to **M/s. Aurobindo Pharma Ltd** 3 API Process Patents
BEST FORMULATION PATENTS AWARD 2018-19	granted to **M/s. Neon Laboratories Limited** 3 Formulation Patents
API PROCESS PATENTS AWARD 2018-19	granted to **M/s. RPG Life sciences Ltd** 2 API Patent
FORMULATION PATENTS AWARD 2018-19	granted to **M/s. Indoco Remedies Ltd** 2 Formulation Patents
PATENT APPRECIATION AWARD 2018-19	granted to **M/s. Micro Labs Limited** 1 Process Patent
IDMA ACG-SCITECH RESEARCH PAPER AWARDS 2019	
REVIEW ARTICLE	Paper: ***'Drug Delivery to Retina: A Review'*** Author(s): **Shelke D. A. and Shirolkar S.** Institute: Department of Pharmaceutics, Dr. D.Y.Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune - 411018, Maharashtra, India.
PHARMACEUTICAL CHEMISTRY	Paper: ***'Synthesis and evaluation of some newer quinazolinonyl substituted benzoxazepinyl / benzothiazepinyl indoles as potent anticonvulsant agents'*** Author(s): **Dr Archana** Institute: Medicinal Chemistry Laboratory, Department of Chemistry, Meerut College, Meerut - 250 001, Uttar Pradesh, India.

NATURAL PRODUCTS	Paper: ***'Extraction, quantitative determination and spectral identification of Carnosic Acid – a diterpene antioxidant from Rosmarinus officinalis'*** Author(s): **Usha Rani N. and Prasad Rao P.T.S.R.K.** Institutes - Department of Freshman Engineering, Prasad V. Potluri Siddhartha Institute of Technology, Vijayawada, Andhra Pradesh - 520 007, India. Department of Chemistry, P. B. Siddhartha College of Arts and Science, Vijayawada, Andhra Pradesh - 520 010, India.
PHARMACEUTICS	Paper: ***'Synergistic Effect of Nigella Oil And Clotrimazole as Ethosomal Gel for Improved Treatment of Fungal Infections'*** Author(s): **Momin M., Butte K. and D'Souza A**. Institutes - Department of Pharmaceutics, SVKM's Dr. Bhanuben Nanavati College of Pharmacy, Mithibai College Campus, V. M. Road, Vile Parle (W), Mumbai – 400 056, Maharashtra, India. Formulation Department, Lupin Ltd, Pune - 411 042, Maharashtra, India. Formulation Development Laboratory, Piramal Enterprises Limited, Light Hall, Chandivali, Powai, Mumbai - 400072, Maharashtra, India.
PHARMACEUTICAL ANALYSIS	Paper: ***'Quantification of Hydrazine Hydrate in Imatinib Mesylate at Genotoxic Level by Chromatographic Method'*** Author(s): **Sojitra C., Agarwal S., Dholakia C., Sudhakar P. and Singh K. K.** Institutes - Cadila Healthcare Limited, API Division, Sarkhej-Bavla N.H. No. 8 A, Changodar, Ahmedabad - 382210, Gujarat, India. Zydus Research Centre, Cadila Healthcare Ltd. Sarkhej-Bavla N.H. No. 8 A, Moraiya, Ahmedabad - 382210, Gujarat, India. Department of Chemistry, Faculty of Science, M.S.University of Baroda, Baroda - 390002, Gujarat, India.
PHARMACOLOGY	Paper: ***'Synthesis and Biological Evaluation of 2-Phenylpyrido [2,3-D] Pyrimidine Derivatives as Cyclin-Dependent Kinase (CDK) Inhibitors'*** Author(s): **Panchabhai V. B., Ingole P. G. and Butle S. R.** Institute: School of Pharmacy, Swami Ramanand Teerth Marathwada University, Nanded-431 606, Maharashtra, India

IDMA INDIAN DRUGS AWARD
Dr. N. Udupa, Ph.D. **Editorial Board, Indian Drugs** In Appreciation of his Valuable Contribution; Consistent, Diligent & Continued Services with Excellence in the Editorial Board of Indian Drugs; Reviewing Research Papers and Judging the Best Papers Published in Indian Drugs; Further Enhancing the Indian Drugs Publication

IDMA J B MODY BEST STUDENTS AWARDS

1.	**Ms. Jyotshnarani Sahoo,** B. Pharm 2018, Siksha O Anusandhan University, Odisha
2.	**Mr. Sangbit Paul,** B. Pharm 2019 , Siksha O Anusandhan University, Odisha,
3.	**Ms. Richa Pravin Rajput,** B. Pharm 2018, SVKM'S NMIMS, School of Pharmacy & Technology Management, Mumbai,
4.	**Ms. Janvhi Machhar,** B. Pharm 2019 , SVKM'S NMIMS, School of Pharmacy & Technology Management, Mumbai,
5.	**Mr. Saravanan B.,** B. Pharm 2018, JSS College of Pharmacy, Ooty,
6.	**Ms. Anusha S,** B. Pharm 2019 , JSS College of Pharmacy, Ooty,
7.	**Ms. Sharada Sairam,** B. Pharm 2019 , JSS College of Pharmacy, Ooty,
8.	**Ms. Kumari Pragya,** B. Pharm 2018 , SVKM'S Dr. Bhanuben Nanavati College of Pharmacy, Mumbai,
9.	**Ms. Amrita Avinash Date,** B. Pharm 2019 , SVKM's Dr. Bhanuben Nanavati College of Pharmacy, Mumbai,
10.	**Ms. Juhi Viraj Salgaonkar,** B. Tech (Pharm) 2018 , Institute of Chemical Technology, Mumbai,
11.	**Ms. Amruta A Dandekar,** B. Tech (Pharm) 2019 , Institute of Chemical Technology, Mumbai, ,
12.	**Ms. Neha Ramesh Pai,** B. Pharm 2018 , Institute of Chemical Technology, Mumbai,
13.	**Mr. Purav Jignesh Shah,** B. Pharm 2019 , Institute of Chemical Technology, Mumbai,
14.	**Ms. Pokar Dhruvisha Jayesh,** B. Pharm 2018, Bharati Vidyapeeth's College of Pharmacy, Navi Mumbai,
15.	**Ms. Pallavi Singh,** B. Pharm 2019, Bharati Vidyapeeth's College of Pharmacy, Navi Mumbai,
16.	**Ms. Mansi Damani,** B. Pharm 2018 , Principal K. M. Kundnani College of Pharmacy, Mumbai,
17.	**Mr. Mayur Jeevan Bansari,** B. Pharm 2019 , Principal K. M. Kundnani College of Pharmacy, Mumbai,
18.	**Ms. Jojiya Grace George ,** B. Pharm 2018 , Amrita School of Pharmacy, Kochi,
19.	**Ms. Meghna M,** B. Pharm 2019 , Amrita School of Pharmacy, Kochi,

20.	**Ms. Swapnali Sanjay Abhale,** B. Pharm 2019, S.N.D.T. Women's University,
21.	**Mr. Nachiket Dandekar,** B. Pharm 2018, Bombay College of Pharmacy, Mumbai,
22.	**Ms Aditi R. Bhat,** B. Pharm 2019 , Bombay College of Pharmacy, Mumbai,
23.	**Ms. Aakriti Sethi,** B. Pharm 2018, University Institute of Pharmaceutical Sciences, Panjab University,
24.	**Ms. Pariksha Oberoi,** B. Pharm 2019, University Institute of Pharmaceutical Sciences, Panjab University,
25.	**Ms. Priti Ramakant Gupta,** B. Pharm 2019, C. U. Shah College of Pharmacy, Mumbai,
26.	**Mr. Neelabh Kashyap,** B. Pharm 2018, Dibrugarh University,
27.	**Ms. Nikita Dey,** B. Pharm 2019, Dibrugarh University,
28.	**Ms. Srilaxmi G. Rao,** B. Pharm 2018, Manipal College of Pharmaceutical Sciences, Manipal,
29.	**Ms. Hawa Bachoo Hashim,** B. Pharm 2019, Manipal College of Pharmaceutical Sciences, Manipal,
30.	**Ms. Keerthana Bhandarkar,** B. Pharm 2019, Manipal College of Pharmaceutical Sciences, Manipal,
31.	**Mr. Shubham Gupta,** B. Pharm 2018, Devi Ahilya Vishwavidyalaya, Indore,
32.	**Mr. Anuj Khandelwal,** B. Pharm 2019, Devi Ahilya Vishwavidyalaya, Indore,
33.	**Mr. Lohith K. C.,** B. Pharm 2019, Acharya & BM Reddy College of Pharmacy, RGUHS University, ,
34.	**Mr. Burhanuddin Idris Kagalwala,** B. Pharm 2018, Oriental College of Pharmacy, Navi Mumbai,
35.	**Ms. Bangar Pratiksha Sitaram,** B. Pharm 2018, Oriental College of Pharmacy, Navi Mumbai,
36.	**Mr. Aditya Ajit Singh,** B. Pharm 2019, Oriental College of Pharmacy, Navi Mumbai,
37.	**Ms. Tanvi Kamat,** B. Pharm 2018, MET Institute of Pharmacy, Mumbai,
38.	**Ms. Shruti Sawant,** B. Pharm 2019, MET Institute of Pharmacy, Mumbai,
39.	**Ms. Shreeya Jadhav,** B. Pharm 2019, Vivekanand Education Society's College of Pharmacy, Mumbai,
40.	**Ms. Nadar Divya Pauldurai,** B. Pharm 2018, H K College of Pharmacy, Mumbai,
41.	**Mr. Patel Zeeshan Feroz Rehana,** B. Pharm 2019, H K College of Pharmacy, Mumbai,

IDMA REPRESENTATIONS IN THE YEAR 2020

Sl. No.	Subject	Date of submission	Representation to
01	Clarification in respect of prescribed electronic modes under Section 269SU of Income Tax Act, 1961	29.01.2020	Chairperson, CBDT
02	Comments on 8th meeting of India-UK Joint Working Group	03.02.2020	Mr. MK Bhardwaj, Deputy Secretary, DoP
03	Practical difficulties which Industries would face from certain provisions of the Union Budget 2020	17.02.2020	Chairman CBDT
04	Uniform Code of Pharmaceuticals Manufacturing Practices	04.03.2020	Deputy Director DoP
05	Hardship faced by ISD registration holder in distribution of Input Tax Credit (ITC) due to technical problems on the Common Portal	12.03.2020	Chairman CBIC
06	IDMA's suggestions on Draft of Drugs and Magic Remedies (Objectionable Advertisement) (Amendment) Bill 2019	16.03.2020	Under Secretary (Drug Regulations), Ministry of Health & Family Welfare.
07	FMRAI's advice to PSRs/ MRs not to attend Work from Home	30.04.2020	Hon'ble Home Minister with CC to Home Secretary, Health Secretary, &Principal Advisor to Prime Minister.
08	Proposed Import Tax on Chemicals and other products	30.04.2020	Secretary (Chemicals) with copies to Secretary, DoP, Secretary (Commerce), and Chairperson, NPPA
09	Industry & Associations comment on cabinet note for Pharma Parks and Production Linked Incentives Scheme	01.05.2020	Dr. Eswara Reddy, Jt. DCI with Copies to Secretary, DoP and DCGI

10	Penal charges levied by Shipping companies	03.05.2020	Hon'ble Sh. Mansukh L Mandaviya, Shipping Minister
11	Processing of import/export permit and route change	08.05.2020	Addl. Secretary (Revenue). Copies also sent to Joint Secretary (Revenue), Director (Narcotics), Director General & Deputy Director General, Narcotics Control Bureau and Narcotics Commissioner, Central Bureau of Narcotics
12	Filing of Quarterly returns for Schedule A Substances	12.05.2020	Narcotics Commissioner, Central Bureau of Narcotics. Copies also marked to Addl. Secretary (Revenue), Joint Secretary (Revenue), DG & DDG, Narcotics Control Bureau
13	Interest Equalisation Scheme on Pre and Post Shipment Rupee Export Credit Extension	13.05.2020	DGFT. Copy of letters also sent to Secretary (Commerce) Secretary, MSME, Finance Secretary and also RBI Governor.
14	Filing of Quarterly returns for Schedule A Substances–RCS Order 2013	01.06.2020	Director General, Narcotics Control Bureau. Copies of letter also sent to Addl. Secretary (Revenue), Joint Secretary (Revenue), Director (NC), Deptt. of Revenue and Deputy Director General (Ops), Narcotics Control Bureau.
15	Processing of Export/Import permits, submission of Demand Drafts and Route Change	01.06.2020	Narcotics Commissioner, Gwalior. Copies also sent to Addl. Secretary (Revenue), Joint Secretary (Revenue) and Director (Narcotics Control), Department of Revenue.
16	Digitalization of Issuance of export permits and facilitation of smooth trade by permitting Route change – Narcotic and Psychotropic substances	10.06.2020	Hon'ble Shri Piyush Goyal, Minister of Commerce & Industry.
17	Comments on Draft Guidelines for dealing cases of discontinuation of Scheduled formulations under Para 21(2) of DPCO 2013	15.06.2020	Deputy Director, NPPA

18	Comments on Draft EIA Notification 2020	23.06.2020	Technical consultant, DoP. Copy also marked to Secretary, DoP
19	Comments on Environment Impact Assessment Notification 2020	23.06.2020	Mr. Rameshwar Prasad Gupta, Secretary, Ministry of Environment, Forest & Climate Change.
20	Delay in Issuing of E-Passes in Tamil Nadu	27.06.2020	Mr. Navdeep Rinwa, Joint Secretary, DoP
21	Custom clearance of Pharmaceutical APIs, KSMs imported from China	29.06.2020	Dr. P.D. Vaghela, Secretary, DoP
22	Custom clearance of Pharmaceutical APIs, KSMs imported from China	30.06.2020	Mr. Shyamal Misra, Jt. Secretary, Commerce
23	Exorbitant Increase in Air freight affecting the exports and Imports	30.06.2020	Secretary, Ministry of Civil Aviation
24	Classification of Alcohol Based Hand Rubs (ABHR) – GST Liability on Hand Sanitizer to be under Drug Category HSN Code 3004	08.07.2020	Chairman, CBIC. Copies sent to Ex-Officio Secretary, GST Council and DCGI.
25	Request to allow import of Palladium and other precious metals on Advance Payment used in production of Drugs and Pharmaceuticals	10.07.2020	Principal Secretary to PM. Similar representations were also sent to RBI Governor, Finance Secretary, Commerce Secretary and Secretary, DoP
26	List of 53 APIs under PLI Scheme with formulations listed in NLEM 2015	10.07.2020	Mr. Navdeep Rinwa, Joint Secretary, DoP
27	Classification of Alcohol Based Hand Rubs (ABHR) – GST Liability on Hand Sanitizer to be under Drug Category HSN Code 3004	10.07.2020	Dr. P.D. Vaghela, Secretary, DoP
28	Unfair tender condition/Fall Clause of seeking “Lowest Rates than quoted to any other institution	13.07.2020	Secretary, DoP

29	Amendment on Notification SO 1223(E), dt.27.3.2020 regarding applicability of same for environment clearance to manufacture intermediate of APIs – B2 Category – Definition of Section 5(f)	17.07.2020	Secretary, MoEF & CC. Copies to Secretary, DoP and Secretary (Health)
30	Comments on India- Peru Trade Agreement	26.07.2020	DoP
31	Processing of Export/Import permits and Route Change	29.07.2020	Narcotics Commissioner. Copies to Addl. Secretary(Revenue), Joint Secretary (Revenue) and Director (Revenue)
32	Processing of Export/Import permit and Route Change – Digitalization of issuance of permits and facilitation of smooth trade by permitting route change	29.07.2020	Addl. Secretary, Revenue. Copies to JS, Dir. (Revenue) & Narcotics Commr, Gwalior
33	Digitalization of issuance of export permits and facilitation of smooth trade by permitting route change	30.07.2020	Minister of Commerce & Industry.
34	Request to allow import of Palladium and other precious metals on Advance Payment used in production of Drugs and Pharmaceuticals	31.07.2020	Ms. Jyoti Sayankrit, Asstt. General Manger (Trade), RBI
35	Ideal Locations for Pharma Parks	03.08.2020	Secretary, DoP. Copies to Joint Secretary, DoP and Dr. Eswara Reddy, Joint DCI.
36	Implementation of Track and Trace system for export of Pharmaceuticals and drug consignments along with maintaining the Parent-Child relationship in the levels of packaging and their movement in supply chain	24.08.2020	Sh. Shyamal Misra, Joint Secretary Commerce

37	Minutes of Interactive session with Hon'ble Shri Mansukh L Mandaviya ji, Minister of State for C & F held on 14th July 2020	26.08.2020	INVEST INDIA
38	Processing of Export/Import permits – Public Notice 05/2020, dt.4.8.2020 and Route Change	26.08.2020	Narcotics Commr. Copies to Addl. Secy (Revenue), Joint Secretary and Director (NC), Deptt. of Revenue
39	Need to reconsider classification of Aerosol Therapy Apparatus (Spray Pump) used in Pharmaceutical products for therapeutic treatment of diseases	27.08.2020	Chairman, CBIC with copy to Secretary, DoP
40	Joint Representation of IDMA & BDMAI on Production Linked Incentive scheme	31.08.2020	Dr. S. Eswara Reddy, Jt. DCI
41	Introductory letter to CEO, FSSAI	02.092020	CEO, FSSAI
42	Request to extend due date for filing of GSTR 9 and GSTR 9C	09.09.2020	Chairman, CBIC with copy to Ex-Officio Secretary, GST Council
43	Classification of Alcohol based Hand Rubs – GST liability on Hand Sanitizers to be under Drug Category HSN Code 3004	11.09.2020	Hon'ble Finance Minister
44	Representation on Unique Quantity Code	11.09.2020	Commerce Secy.
45	Request for anti-dumping measures against possible dumping of Progesterone	18.09.2020	Secretary, DoP
46	Inclusion of Marketer in Drugs & Cosmetics Rules	23.09.2020	DCGI
47	Request for clarification in GSR 2450(E), dt.27.7.2020 – Form 10 validity	28.09.2020	DCGI

48	Clarification of status of Methylcobalamin as ingredient under FSS Regulations 2016	28.09.2020	Chief Executive Officer FSSAI
49	Pathway for Regularization of Kokate Committee approved FDCs including 471 FDCs of Vitamins, Minerals and Micro-nutrients	19.10.2020	DCGI
50	Need for focused webinar to be arranged with MoEF&CC	03.11.2020	Secretary, DoP
51	Revised Guidelines for Production Linked Incentive Scheme, dated 29th October 2020	03.11.2020	DoP
52	IDMA's suggestions for Union Budget 2021-2022	12.11.2020	Joint Secretary (TRU-1) and Joint Secretary (TPL-1). Also to Joint Secretary, DoP
53	Details of Progesterone Manufacturers and manufacturing capacities	16.11.2020	DCGI
54	Representation on Draft on Food Safety and Standard (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Amendment Regulations, 2020-11-23	23.11.2020	CEO, FSSAI
55	Iran Trade settlement through Current Accounts	10.12.2020	Chief Gen. Manager-in-Charge, RBI New Delhi.
56	Request for VC meeting – NDPS – Rationalisation of NDPS Rules and Digitalization of issues of issuance of export permit and facilitation of smooth trade by permitting route change	22.12.2020	Mr. Anurag Singh Thakur, MoS, Finance
57	Digitalisation of issuance of export permit and facilitation of smooth trade by permitting route change – NDPS	22.12.2020	Commerce Secretary

58	Digitalisation of issuance of export permit and facilitation of smooth trade by permitting route change – NDPS	22.12.2020	Deputy Secretary, DoP
59	Need for a focused webinar on Environmental issues	28.12.2020	Mr. Ishtiyaque Ahmed, Advisor NITI Aayog
60	Issues for discussion with DGFT	29.12.2020	Jt. Secretary, DoP
61	Data for Review of Duty Concessions/Exemption on Drugs	29.12.2020	Jt. Secretary, DoP
62	Request for including pharmaceutical industry workforce in the priority list for Covid 19 Vaccination	30.12.2020	Dr. Vinod Paul, Member, NITI Aayog

MEETINGS / WEBINAR MEETINGS IN 2020

Date	Subject
	January 2020
14.01.2020	Meeting with stakeholders to review IP Acts
21.01.2020	Meeting with Hon'ble Mr. Raj Kumar Singh, Minister of State for Skill Development & Entrepreneurship
23.01.2020	Session on The UAE-India Trade Bridge
24.01.2020	Interaction with Brazilian Business delegation
28.01.2020	Meeting with Mr. Surinder Pal Singh, Joint Secretary, Deptt of Economic Affairs
31.01.2020	Meeting on Impact on import of APIs from China due to Corona Virus
	February 2020
03.02.2020	Meeting on APIs wrt Supplies from China
06.02.2020	Meeting regarding impact of Chinese lock down due to Corona virus on supply of APIs/KSMs to India
17.02.2020	Meeting on APIs / Corona Virus Meeting to review implementation of UCPMP 5th meeting of Task Force on Active Pharmaceutical Ingredients
19.02.2020	Meeting to discuss various options for domestic manufacturer of critical APIs in which India is critically dependent on imports Progress in the developing of Web Portal for authentication of Pharma Exports

20.02.2020	IDMA delegation meetings with the following: • Dr. P.D. Vaghela, Secretary, DoP • Mrs. Shubhra Singh, Chairperson, NPPA • Mrs. Ritu Dhillon, Member Secretary, NPPA • Dr. V G Somani, DCG(I) and • Dr. Mandeep K Bhandari, Joint Secretary (Health)
	March 2020
03.03.2020	Meeting to finalise the white paper titled "Securing access to essential medicines'
11.03.2020	Novel Coronavirus meeting to build up a comprehensive and robust response system
12.03.2020	Meeting on COVID-19 Meeting on Production Linked Incentive Scheme
	APRIL 2020
04.04.2020	Webinar with Mr. Shyamal Misra, JS Commerce – on stock position of APIs and availability vis-a-vis requirements
21.04.2020	VC meeting with Pharma and Medical Device manufacturers' Associations – Chaired by Secretary, DoP
28.04.2020	IDMA Executive Committee meeting Videoconference with select Industry Associations by Hon'ble CIM
29.04.2020	"Creating a Resilient & Future-Ready Supply chain"
	MAY 2020
12.05.2020	Webinar on Impact of Covid19- How the Indian Pharma industry should respond, reset and reshape"_
25.05.2020	Webinar of DoP with MoEF officials
26.05.2020	VC with stakeholders to discuss the schemes related to bulk drug and medical device on 26.05.2020 under the Chairmanship of Secretary (Pharma)
29.05.2020	IDMA Executive Committee meeting
30.05.2020	Webinar on Resetting the entrepreneurial mindset for the new normal
	JUNE 2020
04.06.2020	VC Meeting to discuss the proposed draft Notification on Environment (Protection) Amendment Rules, 2019 dated 23rd January, 2020 of M/o EF&CC-
06.06.2020	Webinar on Mind is Medicine by Dr. Mickey Mehta
10.06.2020	Video Conference Interaction with Pharma Industry under the chairmanship of Hon'ble Minister of CIM – CIM Minister, MoS, C&F Minister and MoS attended

23.06.2020	CDSCO Webinar on formulation of guidelines for labelling of performance enhancing drugs (Doping drugs)
25.06.2020	VC to discuss the notifications on environmental standards and environmental clearances issued by M/o EF&CC and their impact on pharmaceutical industry
26.06.2020	IDMA Executive Committee meeting
29.06.2020	Webinar on Production Linked Incentives
	JULY 2020
14.07.2020	Video conference with Hon'ble Mansukh L Mandaviyaji, MoS, C&F
16.07.2020	Consultation meeting with stakeholders on finalization of draft notification on Schedule M
17.07.2020	DGFT issues and opportunities to promote pharmaceutical exports
27.07.2020	Follow-up meeting with Minister of CIM
31.07.2020	IDMA Executive Committee meeting
	August 2020
01.08.2020	Emerging Regulatory & Pharma Scenario Internationally and in India -- Speaker: Mr. Nagesh Nanda, Former Director – Global R&D CHEMO, Spain
06.08.2020	USP COVID-Connect Prof. Muhammad Zaman
13.08.2020	Meeting with Kyrgyzstan Commercial Consulate @ our office
17.08.2020	**National Consultation meeting for revision of NLEM 2015** **National Consultation meeting for revision of NLEM 2015**
19.08.2020	IDMA Excise & Taxation Committee and L & S Webinar on "GST, Customs & Income Tax Implications on the Pharmaceutical Industry **How to keep my factory running without stoppage?** **How to safeguard workers from Covid-19?**
20.08.2020	**How to keep my factory running without stoppage?** **How to safeguard workers from Covid-19?**
21.08.2020	Meeting to Review implementation of UCPMP Second meeting of Forum of Pharma Associations
26.08.2020	Pharmaceuticals **"The Road Ahead"**
28.08.2020	IDMA Executive Committee meeting
29.08.2020	IDMA – iMedrix Webinar on "Telemedicines Applications for Physician Engagement During #COVID Times"
	September 2020
04.09.2020	Webinar on "HUMAN ERROR - INVESTIGATIONS & REDUCTION

07.09.2020	Meeting to make a plan to fill the gap between the Department and Pharma & Medical Device Clusters and also to ensure linkages of these clusters with academia such as NIPERs
25.09.2020	IDMA Executive Committee meeting
29.09.2020	Felicitation to Dr. P.D. Vaghela, IAS
	October 2020
07.10.2020	Meeting to review Action Taken Report on 9th meeting of the India EU Joint Working Group on Pharmaceuticals, Bio-technology and Medical Devices held at Brussels and to discuss new agenda points
13.10.2020	Production Linked Incentives (PLI) Scheme for promoting manufacturing of chemicals/building blocks/intermediates which are imported in very high value, have high export potential and are key raw material for highly exported chemicals
21.10.2020	Meeting of Regulatory Affairs sub-committee
22.10.2020	Finalization of draft Rules GSR 354(E), dt.5.6.2020 – New Drugs & Clinical Trial Rules 2019
30.10.2020	IDMA Executive Committee meeting
	November 2020
10.11.2020	Virtual meeting of IDMA Nutraceuticals Sub-committee
17.11.2020	Discussions on PLI Scheme by Secretary, DoP with select members
18.11.2020	Discussions on revised PLI scheme
19.11.2020	Virtual meeting of IDMA Nutraceuticals Sub-committee
24.11.2020	VC meeting under the Chairmanship of Hon'ble CIM Mr. Piyush Goyal with Chambers of Commerce & Industry Associations
26.11.2020	Web meeting by Secretary, DoP on PLI with IDMA & BDMAI
27.11.2020	IDMA Executive Committee meeting
30.11.2020	VC meeting on MoEF issues
	December 2020
02.12.2020	Board of Trade meeting Chaired by Hon'ble CIM
07.12.2020	Hon'ble CIM VC Meeting with Industry Associations on New Foreign Trade Policy
07.12.2020	Meeting with Mr. Rajneesh Tingal, Joint Secretary, DoP to discuss pricing issues
09.12.2020	VC meeting on Standards for Pharma Industry -- DoP & MoEF Inter-departmental meeting with Tech experts from BDMA and IDMA

10.12.2020	VC meeting between Secretaries of DoP and MoEF – IDMA & BDMA
11.12.2020	PLI --- Internal Expert committee meeting PLI – VC meeting official Pre-Budget meeting with IDMA – Finance Ministry
18.12.2020	IDMA Executive Committee meeting IDMA Executive committee members meet with Mr. Arun Singhal, CEO, FSSAI
22.12.2020	Consultation session under the chairpersonship of Ms. Sumita Dawra, Additional Secretary, DPIIT regarding Investment Clearance Cell (ICC)/ National Single Window System
23.12.2020	VC meeting on Review of Duty Concessions/Exemptions on Drugs – Chair Mr. Navdeep Rinwa, JS, DoP
30.12.2020	Web meeting with Mr. Mansukh L Mandaviya on PLI Scheme

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 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

CONSULTANTS

S W Deshpande	Regulatory matters
Chetan Doshi	Account / Finance
Dr S G Deshpande	Indian Drugs
S P Deo	Trade matters
Shailesh Sheth	Indirect Taxation
Bakul Mody	Direct Taxation

VOICE OF THE NATIONAL SECTOR

IDMA THEMES

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)

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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