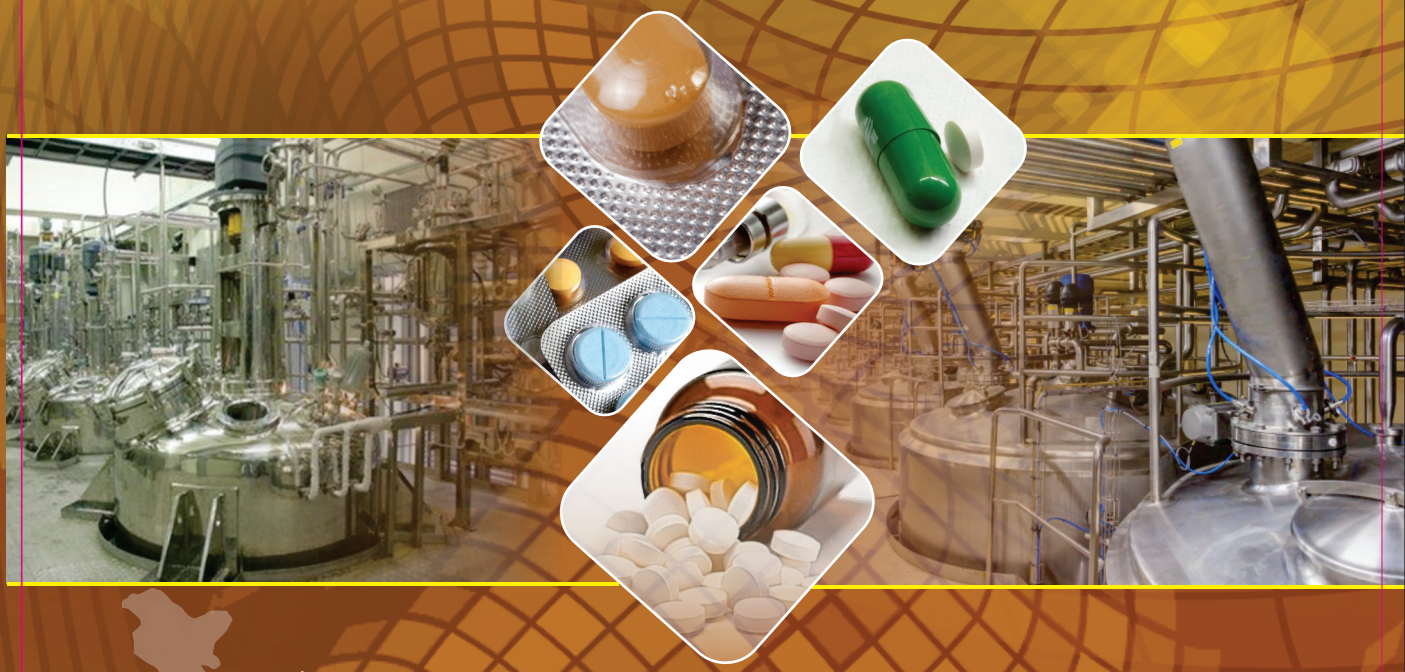
INDIAN DRUG MANUFACTURERS' ASSOCIATION

Indian APIs & Formulations for Global Healthcare



ANNUAL REPORT

58th

2018-19

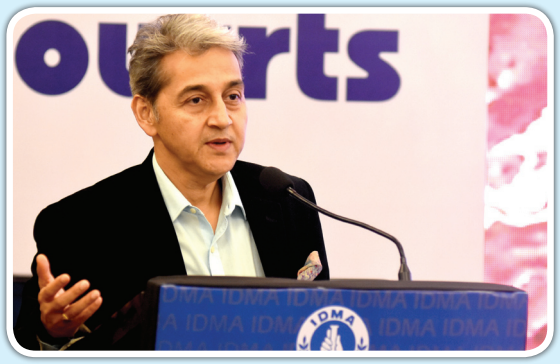
Delivering Healthcare...to the World !!

Glimpses of IDMA 57th Annual General Meeting & Annual Day Celebrations 2019

IDMA 57th AGM in progress on 19th January 2019 at Hotel St Regis, Lower Parel, Mumbai. On the dais (from L to R) Shri S V Veerramani, Immediate Past National President, Shri Deepnath Roy Chowdhury, National President, Shri Daara B Patel, Secretary-General, Shri Mahesh H Doshi, Vice President, (Western Region), Shri Bharat Shah, Hon General Secretary and Dr George Patani, Hon Treasurer

Shri Deepnath Roy Chowdhury, National President delivering the Presidential address at 57th Annual Day Celebrations 2019

Dr Mandeep K Bhandari, IAS, Joint Secretary, Ministry of Health & Family Welfare addressing the participants



Shri Sudhansh Pant, IAS, Joint Secretary, Ministry of Health & Family Welfare delivering his address

Chief Guest Dr Vinod Paul, Member, NITI Aayog addressing the participants

Shri Ameesh Masurekar, Director – AIOCD AWACS delivering his Keynote address and presentation

N O T I C E

The 58th Annual General Meeting of the Indian Drug Manufacturers' Association will be held on **Saturday, 18th January 2020 at 3:30 p.m. at Hotel St Regis, Mumbai** to transact the following business:-

AGENDA

1. To read the Notice convening the meeting
2. To adopt the Annual Report for the year 2018-19
3. To adopt the audited Statement of Accounts for the year ended 31st March 2019
4. To appoint auditors for the year 2019-20
5. Welcoming of Incoming National President by the Outgoing National President
6. Any other business with the permission of the Chair.

Daara B Patel
Secretary - General

Date : December 20, 2019

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 15th January 2020.*

Members are requested to register and be present at the Annual Day Celebrations at the same venue at 5.30 p.m.

IDMA EXECUTIVE COMMITTEE 2019

NATIONAL PRESIDENT	**DEEPNATH ROY CHOWDHURY** *Managing Director* **Strassenburg Pharmaceuticals Ltd.** 70 Hazra Road, Kolkata – 700 019
IMMEDIATE PAST NATIONAL PRESIDENT	**S. V. VEERRAMANI** *Chairman & Managing Director* **Fourrts (India) Laboratories Pvt. Ltd.** No.1, Fourrts Avenue, Annai Indira Nagar Okkiyam Thoraipakkam Chennai – 600 097.
SR. VICE-PRESIDENT	**MAHESH H. DOSHI** *Partner* **Dy-Mach Pharma** B-12, Anand Sagar, Old Nagardas Road, Andheri (E), Mumbai – 400 069.
VICE-PRESIDENTS	
Western Region	**DR VIRANCHI SHAH** *Director* **Saga Laboratories** Survey 198/2-3, Chachrawadi, Besides Claris, Sarkhej Bawla Highway, Changodar, Ahmedabad - 382 210.
Northern Region	**B. R. SIKRI** *Director* **Next Wave (India)** **Auronext Pharma P. Ltd.** C-980, Sushant Lok, Phase – I, Gurgaon – 122 002
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 Apartment, 14A Manohar Pukur Road, Kolkata - 700 026.
HON. GENERAL SECRETARY	**BHARAT N SHAH** *Managing Director* **S. Kant Healthcare Ltd.** 3-A, Shiv Sagar Estate, Dr. Annie Besant Road, Worli, Mumbai – 400 018.
HON JOINT SECRETARY	**SIDDHARTHA PAUL** *Executive Director* **Palsons Derma Pvt. Ltd.** 10/D/1, Ho-Chi-Minh Sarani, Kolkata - 700 071.
HON JOINT SECRETARY	**BHAVIN MUKUND MEHTA** *Director* **Kilitch Co. (Pharma) Ltd.** Unit No. 37, Ujagar Industrial Estate, 3rd floor, W.T. Patil Marg, Deonar, Mumbai 400 088.
HON. TREASURER	**DR. GEORGE A. PATANI, Ph.D.** *Director* **INGA Laboratories P. Ltd.** Inga House, Mahakali Road, Andheri East, Mumbai 400 093.
ELECTED MEMBERS	**ASHOK DHOKA** *Director* **Maxim Pharmaceuticals Pvt. Ltd.** 08, Kshitij Co-op. Hsg Society, Opp. Sambhavnath, Jain Mandir, Behind Maharshi Nagar Police Chowky, Salisbury Park, Pune - 411 037.

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

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

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

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

JAY MEHTA
Sr. Vice President –International Division
J.B. Chemicals & Pharmaceuticals Ltd.
Cnergy IT Park, Unit A, 8th Floor,
Appa Saheb Marathe Marg, Prabhadevi,
Mumbai - 400 025

KAMLESH C. PATEL
Managing Director
West-Coast Pharmaceuticals Works Ltd.
Meldi Estate, Nr. Prasang Party Plot,
Opp. Sola Bhagwat, Sayona City Road,
Gota, Ahmedabad – 382 481.

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

MEHUL M. SHAH
Founder & Managing Director
Encube Ethicals Pvt. Ltd.
Unit No. 24, Steelmade Industrial Estate,
Marol Village, Andheri (East),
Mumbai – 400 059.

PRAKASH MUDDA
President (Corporate Projects & Operations)
Micro Labs Limited
No.27, Race Course Road,
Bangalore - 560 001.

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.

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

VASUDEV KATARIA
Director
Vindas Chemical Industries P. Ltd.
210 Adamji Building, 413,
Narsi Natha Street,
Masjid Bandar Road, Mumbai 400 009.

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

CO-OPTED MEMBERS

KAL SUNDARAM
CEO – India, Emerging & CHC
Sun Pharma Laboratories Ltd
Sun House, 201 B/1,
Western Express Highway,
Goregaon (East), Mumbai– 400 063

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

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

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

PANKAJ R. PATEL
Chairman & Managing Director
Cadila Healthcare Ltd.
Zydus Tower, Satellite Cross Road,
Ahmedabad – 380 015.

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

ATUL J. SHAH
Executive Director
Ellis Pharma P. Ltd.
Plot No.4, GIDC, Behrampura
Opp. Khodiyar Nagar, BRTS Bus Stand
Behrampura, Ahmedabad - 380 022.

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

SPECIAL INVITEES

ADITI KARE PANANDIKAR
Managing Director
INDOCO REMEDIES LIMITED
Indoco House, 166 C.S.T. Road,
Santacruz (E), Mumbai - 400098

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.

BAL KISHAN GUPTA
Chairman
Medicamen Organics Ltd.
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Delhi -110 052.

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

C. V. VENKATARAMAN
Director – Corporate Services
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Corp. Office: Plot No.C-25, Laxmi Tower,
'B' WIng, BandraKurla Complex,
Bandra (East), Mumbai - 400 051.

DR. AMIT RANGNEKAR
Vice President,
Centaur Laboratories
CENTAUR HOUSE
Opp. Grand Hyatt,
Vakola, Santacruz - East,
Mumbai - 400 055

DR. R. K. SANGHAVI
Sr. Consulting Clinician. Advisor - Positive Health Expert, Healthcare - Pharma & Nutra Neuro Marketing & Techno Regulatory
Inventia Healthcare Pvt. Ltd.
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Santacruz (West), Mumbai - 400 054.

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

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

KAPIL BHARGAVA *(Expired on 19th March 2019)*
Former Deputy Drugs Controller (India)
104, K-52, Yogi Nagar,
Borivali (W), Mumbai - 400 091.

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

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

DR. DINESH DUA
Chairman, PHARMEXCIL &
CEO & Director, Nectar Lifesciences Ltd.
Pharmaceuticals Export Promotion
Council of India & Aurobindo Pharma Ltd
101, Aditya Trade centre,
Ameerpet, Hyderabad - 500 038.

MOHAN JAIN
Director
Naprod Life Sciences Pvt Ltd
Unit No.803, 8th Floor, Lodha Supremus IT Park,
S.B. Marg, Railway Colony,
Lower Parel, Mumbai - 400013

NANDAN M CHANDAVARKAR
Joint Managing Director
FDC Limited
142/48 S.V. Road,
Jogeshwari (W), Mumbai 400 102.

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

NIRAV K. MEHTA
Director
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Corona House, “C” Mondeal Business Park,
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Ahmedabad – 380 059.

PRANABH MODY
President
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Mumbai - 400 025

PRANAV CHOKSI
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Dorr Oliver House, 2nd Floor,
B.D. Sawant Marg, Chakala,
Andheri (E), Mumbai-400 099.

RAJESH GUPTA
Managing Director
Dallas Formulations Pvt. Ltd.
815-A, N.A.C, Manimajara,
Chandigarh (U.T) - 160 101
144, DIC, Industrial Area,
Nr. Sai Road, Baddi (H.P)

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

SACHIN N. DOSHI
Director
DWD Pharmaceuticals Ltd.
Dalamal House, 404, 4th Floor
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Mumbai-400 021.

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

SANDEEP GUPTA
Vice President – BD, Strategy &
Corporate Affairs
(Regulatory Legal & Govt. Relations)
Geltec Private Limited/
Universal MedicarePvt.Ltd.
Capsulation Premises Deonar, Sion Trombay Road,
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SHIV SAGAR TIWARI
Director
Burnet Pharmaceuticals (P) Ltd.
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RAVI UDAYA BHASKAR
Director General
Pharmaceuticals Export Promotion Council of India (Pharmexcil)
101, Aditya Trade Centre, Ameerpet,
Hyderabad - 500 038.

VINAY PINTO
Executive Director
Wallace Pharmaceuticals P. Ltd.
B–307/312, Floral Deck Plaza,
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YASHWANT C. PATEL
CMD
Elysium Pharmaceuticals Ltd
Post: Dabhasa, Tal. Padra
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CORPORATE MEMBERS

AJIT DAMLE
Business Head, South Asia
DSM Nutritional Products India Pvt. Ltd.
401, 4th Floor Windsor House, CST Road Kalina,
Mumbai 400098

AMIT PARASMAL BOHORA
Managing Director
Biosensors Interventional Technologies (India) Pvt. Ltd.
Plot No. 14, Shed No. A-2, Near Charak Pharma,
GIDC Umbergaon,
Dist. Valsad- 396 171.

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

ARVIND IYER
Chairman & Managing Director
Premier Nutraceuticals Pvt Ltd.
714/715 Midas, Sahar Plaza, Andheri - Kurla Road,Andheri (East)
Mumbai - 400059

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

D.C. JAIN
Chairman
Akums Drugs & Pharmaceuticals Ltd.
304, Mohan Place, Lsc, Block C,
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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,
Lower Parel (W), Mumbai 400 013, India.

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

K. M. PRASAD
Managing Director
Karnataka Antibiotics and
Pharmaceuticals Limited
"Nirman Bhavan", Dr.Rajkumar Road,
1st Block, Rajajinagar,
Bangalore 560 010.

KAPIL JHAVERI
CMD
TIL Healthcare Pvt. Ltd.
Jhaver Centre, R.A. Building,
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K. DEVASENAPATHI
Director
Ishaana Nutraceuticals Pvt Ltd
G-47& G 86, UPSIDC, Selaqui,
Dehradun - 248 197.

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

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

S. ABHAYA KUMAR
Managing Director
Strides Shasun Limited
3rd & 4th Floor, 'Batra Centre',
28, Sardar Patel Road, Guindy,
Chennai 600 032

S. CHATTERJI
Technical Adviser
Parenteral Drugs (India) Ltd.
340, Laxmi Plaza, New Link Road,
Andheri (W), Mumbai - 400 053.

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

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

SUDHIR VAID
Chairman & Managing Director
Concord Biotech Limited
403, Iscon Elegance, 4th Floor, Prahladnagar Cross Road, S.G. Highway, Ahmedabad-380 015. (India)

T. SATHISH
General Manager –Corporate Support
Tablets (India) Limited
Jhaver Centre, 72, Marshalls Road,
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Mr. Anil Kumar Srivastava
(VP & SBU Head)
Jubilant Life Sciences Limited
1st Floor, Transocean House,
Lake Boulevard road,
Hiranandani Business Park
Branch Office, Powai, Mumbai-400076

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

AJAY BHARADWAJ
Chief Executive Officer
Anthem Bioscience Private Limited
No 49, Canara Bank Road,
Bommasandra Industrial Area,
Phase 1, Hosur Road,
Bengaluru 560099

PATRON MEMBERS

DR. VIVEK V. PALKAR
Chairman & Managing Director
Nivedita Chemicals Pvt. Ltd.
Anek Prayog Pvt. Ltd.
A-14, M.I.D.C., Andheri (E),
Mumbai - 400 093.

JAYASHREE NAIR
Chairperson & MD
BDH Industries Ltd.
Nair Baug, Akurli Road,
Kandivali (E), Mumbai-400 101

JAYESH P. CHOKSI
C.M.D. / President
Gufic Biosciences Limited
Dorr Oliver House, 2nd Floor,
B.D. Sawant Marg, Chakala,
Andheri (E), Mumbai-400 099.

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

EX-OFFICIO MEMBERS
(PAST PRESIDENTS)

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

J. B. MODY
Chairman & Managing Director
J. B. Chemicals & Pharmaceuticals Ltd.
Cnergy IT Park, Unit A1, 8th Floor,
AppaSahebMarathe Marg,
Prabhadevi, Mumbai 400 025.

CHANDRAKANT I. GANDHI
Chairman
Gentech Laboratories Ltd.
Unit No.803, 8th Floor,
Lodha Supremus IT Park,
S.B. Marg, Railway Colony,
Lower Parel, Mumbai - 400013

N. I. GANDHI (Expired on 10th July 2019)
Chairman & Managing Director
Lyka Labs Limited
101, Shiv Shakti Industrial Estate,
Andheri Kurla Road, Andheri (E),
Mumbai - 400 059.

ANANT R. THAKORE
Managing Director
Avik Pharmaceutical Ltd.
194, Arvind Chambers,
Gauri Studio Compound,
Western Express Highway,
Andheri (E), Mumbai - 400 069.

DINESH B. MODY (Expired on 28th August 2019)
Whole-Time Director (Administration)
J. B. Chemicals & Pharmaceuticals Ltd.
Cnergy IT Park, Unit A2, 3rd Floor, Unit A,
8th Floor, Appa Saheb Marathe Marg,
Opp.Tata Motors, Prabhadevi,
Mumbai 400 025.

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 / HON. CHAIRMAN
Gopakumar Nair Associates/ GNANLex
3rd Floor, "Shivmangal", Next to Big Bazar,
Akurli Road, Kandivli (E), Mumbai - 400 101.

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

YOGIN R. MAJMUDAR
Managing Director
Bakul Aromatics and Chemicals Ltd.
Sterling Center,
4th Floor Dr. A. B. Road,
Worli, Mumbai - 400 018.

SURESH G. KARE
Chairman
Indoco Remedies Ltd.
Indoco House, 166, C.S.T. Road,
Santacruz (E),
Mumbai - 400 098.

B. N. SINGH
Executive Chairman
Alkem Laboratories Ltd.
Alkem House, S. B. Road,
Lower Parel (W), Mumbai - 400 013.

N. R. MUNJAL
Vice Chairman-cum-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.
105, 1st Floor, Rewa Chambers,
31, New Marine Lines,
Mumbai – 400 020.

GUJARAT STATE BOARD

Chairman

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

Hon. Secretary

DR. SHRENIK K SHAH
Hon. Secretary
Montage Laboratories Pvt. Ltd.
At-Dhandha, Idar Road,
Himatnagar 383 001.

Executive Secretary

MR RAJIV SHAH
IDMA GSB
4 Park Avenue, 1st Floor,
Parimal Garden Cross Road,
Nr. Gujarat Gas Co,
Ellisbridge, Ahmedabad 380006

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
Director
Next Wave (India)
Auronext Pharma Pvt. Ltd.
C-980, Sushant Lok, Phase – I,
Gurgaon – 122 002

KARNATAKA STATE BOARD

Chairman

S. M. MUDDA
Managing Director
Mison Labs
Malta & Mumbai

Hon. Secretary

VIPIN KUMAR
Managing Director
Tejkamal Pharmaceuticals Pvt Ltd
39/2, Santoshima Enclave, B Block,
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T Dasarahalli, Tumkur Road,
Bangalore - 560 057

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.
New No. 25, 12th Cross Street
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Hon. Secretary

T. SATHISH
General Manager – Corporate Support
Tablets (India) Limited
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Chennai – 600 008.

Executive Secretary

S. KRISHNAN
Block-D1, Baid Metha Complex
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Little Mount, Saidapet,
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TELANGANA STATE BOARD

Chairman

SHAIK JANIMIYA
Managing Director
Crescent Therapeutics Ltd
Crescent Towers, H. No. 4-7-11/4/B,
Raghavendra Nagar, Nacharam,
Hyderabad - 500 076.

Hon. Secretary

M SOMESWARA RAO *(5th May 2018 onwards)*
Managing Director
Sumages Pharma Pvt. Ltd.
Industrial Estate, Bhimavaram West,
Godhavari, Andhra Pradesh 534 201

WEST BENGAL STATE BOARD

Chairman

UTPAL MOITRA
Director
Emcee Pharmaceuticals P. Ltd.
DA-201, Sector – I,
Ground Floor, Salt Lake City,
Kolkata – 700 064.

Hon. Secretary

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

IDMA COMMITTEE CHAIRMAN 2019

Sr. Nos.	Sub-Committee	Chairman	Vice Chairman
1.	Bulk Drugs	**Yogin R Majmudar** Bakul Aromatics and Chemicals Ltd.	**Neha Thakore** Avik Pharmaceutical Ltd
2.	Contract Manufacturing	**Mehul Shah** Encube Ethicals Pvt Ltd	**Pratik Kamani** Encube Ethicals
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 Ltd.	**Prakash Rijhwani** Blue Cross Laboratories Ltd. (Nashik)
5.	Finance & Administration	**Bharat N Shah** S Kant Healthcare Ltd.	**B G Barve** Blue Cross Laboratories Ltd.
6.	I P R	**Dr Gopakumar G Nair** Gopakumar Nair Associates	**Shrikant Sharma** Duphar
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)	**Dinesh B Mody** JB Chemicals & Pharma. Ltd.	**Dr Viranchi Shah** Saga Laboratories
10.	Marketing	**Vinay Pinto** Wallace Pharmaceuticals Ltd.	**S. R. Vaidya** Bliss GVS Pharma Ltd.
11.	Medical	**Dr R K Sanghavi**	**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** Sunayan Pharmaceuticals	**Tushar A. Korday** Emil Pharmaceutical Inds. Pvt. Ltd.
14.	NDPS	**M. Devesh** Embio Ltd.	**Mr.Ram Sundaram** Head of Regulatory Affairs, Abbott

15.	Nutraceuticals	**Dr R K Sanghavi**	
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**
19.	Quality Management & Technical	**Dr. Milind Joshi** J. B. Chemicals & Pharmaceuticals Ltd.	**Dr. Gaurav Pathak** Glenmark Pharmaceuticals Ltd.
20.	Regulatory Affairs	**S M Mudda**	**S W Deshpande**

SECRETARIAT

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S RANGANATHAN
Assistant Manager (Administration)
Email : **idmadelhi@gmail.com**

58th Annual Report 2018-19

Dear Member,

This 58th Annual Report covers varied activities, initiatives and achievements by your Association during the last year. This has been possible due to the leadership, guidance and support provided by our National President, Past Presidents, Office-Bearers, our very active State Boards, the Chairmen, Vice-Chairmen & Members of various Committees and our consultants / advisors. Due to their efforts and our interactions with the concerned Officials & Ministers, we have been able to make effective recommendations and representations to the government and have successfully managed to get many issues resolved in our Industry's favour. We continue to be known as "Voice of the National Sector" and will always be the apex body of Pharmaceutical and API Manufacturers in the country. IDMA is the only Association which supports and caters to the needs of the cross section of the industry, namely the Micro, Small, Medium and Large manufacturers. We actively support the Formulation, API and Nutraceutical industries.

IDMA wins Indian Pharma Swachhta Champion Award

At the 4th India Pharma & Medical Device Awards held on 18th February 2019 at Bengaluru, IDMA was bestowed with the first-ever ***Indian Pharma Swachhta Champion Award*** *by the Hon'ble Minister for Chemicals and Fertilisers Shri D.V. Sadananda Gowda and Hon'ble Minister of State Shri Mansukh L Mandaviya. IDMA won the Award among other participants for the cleaning up activities by IDMA Secretariat at the BYL Nair Charitable Hospital, Mumbai, a Government run institution.*

Floods – Disaster Relief

Many parts of the country were inundated with floods. We received an urgent S O S from Dr V G Somani, DCG(I) seeking IDMA's support by way of medicines for flood affected places in Maharashtra. We initiated immediate action and supplied medicines to designated places as requested by Government. We also responded to appeals from Kerala Government for supply of medicines for the flood affected people.

56th Indian Drugs Annual Day Celebrations

Indian Drugs Journal and the IDMA IPR Committee jointly organised the Indian Drugs 56th Annual Day Celebrations along with the Indian Education Society (IES) on 22nd March 2019 at their campus at Bandra, Mumbai. There was excellent participation of over 120 delegates. The theme of the Celebrations was 'Innovation in Pharma Research: An Indian Perspective'. The Chief Guest was Dr Ahmed Kamal, FNASc, FAPSc, FRSC, Pro Vice Chancellor Jamia Hamdard University. The Guests of Honour were Dr Madhu Dikshit, FNA, FNASc, FASc, FAMS, JC Bose National Fellow, THSTI National Chair, NCR Biotech Science Cluster and Dr Premnath V., Head, NCL Innovations National Chemical Laboratory, Pune. The event is covered in detail in the Publications section.

NPPA order for 50% increase to certain formulations under Para 19 of DPCO 2013

The Standing Committee on Affordable Medicines and Health Products (SCAMHP) under NITI Aayog recommended that there was a need to revisit the prices of 12 formulations presented to it for upward price revision under para 19 of DPCO 2013 by allowing one-time 50% increase from the present ceiling price. NPPA included another 9 formulations, as recommended by NITI Aayog. NPPA noted that these 21 scheduled formulations being considered for upward price revision under para 19 of DPCO 2013 were low priced drugs and were under repeated price control. Most of these drugs were being used as first line of treatment and as they are crucial to the public health program of the country. This matter is covered in detail in the Pricing / Consumer Affairs section.

Plastic Waste Management - Ban of Single Use Plastics

Following Hon'ble Prime Minister Shri Narendra Modi's call to shun single use plastics (SUP) nation-wide, Government planned national campaign under "Swachhta Hi Seva" initiative. The Association had received circular from Department of Pharmaceuticals on this initiative with their Action Plan for industry. The Department requested industry to mobilize their employees to undertake Shramdaan for collection and disposal of plastic waste on 2nd October 2019 to mark 150th birth anniversary of Mahatma Gandhi. We conveyed this initiative to all Members by email on 23rd September for their information and necessary action.

MSME Minister Nitin Gadkari request to plant trees

Shri Nitin Gadkari, Minister of Road, Transport & Highways and Micro, Small & Medium Enterprises (MSME) sent us a letter dated 12th July 2019 for requesting our Members to plant as many trees as possible before the monsoon season ended. The trees were to be of local variety, indigenous to the area like Neem, Peepal, fruit bearing trees etc and also to ensure that the trees survive. The plantations were to be near National Highways, State Highways and even district roads. We published the letter in IDMA Bulletin issue dated 30th July 2019 for information of Members. A number of our Members adhered to this request.

Rise in Anti-Microbial Resistance

We received a letter from Department of Pharmaceuticals dated 11th October 2019 about the rise in Anti-Microbial Resistance (AMR) due to pharmaceutical pollution resulting in development of 'superbugs'.The CPCB had set up an Expert Committee last year to draft standards for antibiotic residue and we had provided substantial inputs. DOP estimated that as of 2014, nearly 700,000 people lost their lives to resistant infections every year globally. DoP requested manufacturers to sell and manufacture responsibly and take steps to remove antibiotic residue from their effluents as an initial step towards AMR containment.The letter was published in IDMA Bulletin dated 30th October 2019 for information and necessary action by Members and industry. This matter is covered in detail in the Bulk Drugs section.

As we go to press, we have just received a circular dated 23rd December 2019 from Dr V G Somani, DCG(I) about 'Rational use of Antibiotics for Limiting Antimicrobial Resistance'. The DCG(I) has informed that, as a part of their overall responsibility for ensuring the safetyof public health and limiting development of AMR, the CDSCO and Ministry of Health and Family Welfare have been continuously taking various regulatory steps to curb and control indiscriminate use of antibiotics. The DCG(I) has also requested all stakeholders to join hands in rational use of antibiotics to adhere to the mission of use of medicines appropriately to safeguard safety and well-being of patients.

IDMA Representation on LSSSDC Governing Council

We received an invite (by email dated 19th June 2019) from Life Sciences Sector Skill Development Council (LSSSDC) to propose a nominee from IDMA to join the Governing Board of LSSSDC. As proposed by National President, the Executive Committee nominated Mr Daara Patel, Secretary-General to represent the Association on the Governing Board.

Forum of Associations Meeting

We participated in the 6th Forum of Pharmaceutical Associations meeting chaired by Dr Eswara Reddy, DCG(I) on 24th June 2019. It was well attended with officials from CDSCO and participation by other Associations. We discussed some key issues such as:

- ***Unregulated supply of APIs:** we were informed that CDSCO had conducted raids across the country in the premises of various firms dealing in APIs to verify their compliance to the provisions under Drugs and Cosmetics Act and Rules. It was found that many drugs, whose source could not be established, were distributed by some unregistered companies to various manufacturers in the country. As requested by DCG(I), we published the circular in IDMA Bulletin dated 30th June 2019 for information and requesting Members to comply with all labelling requirements and to immediately inform the DCG(I) office in case any API procured from these firms was received with incomplete label information.*
- ***Repacking of APIs:** we discussed various options on repacking of APIs such as the need for repacking Licence, guarantee of quality, smaller packings etc.*
- ***Proposed revision of Schedule M:** We requested that since the draft notification was mainly based on WHO guidelines, only a limited part should be made mandatory and rest retained as guidelines. Our suggestions on Schedule M is covered in detail in the Regulatory Affairs section.*
- ***Track and Trace:** We highlighted the different directives emanating from Departments of Commerce, DOP and Health on implementing Track and Trace. We also highlighted the need to streamline and unify the proposals to ease implementation. Further details are covered in the International Trade & Customs and Regulatory Affairs sections.*

A number of meetings were also held with various State FDAs, CDSCO Zonal offices, State PCBs etc. to discuss local issues.

DCG(I) updating list of New Drugs

Dr V G Somani, DCG(I) issued a circular dated 18-10-2019 informing that CDSCO was updating the list of New Drugs by collecting information from old registers/files and other sources. To ensure that the list included all approvals, DCG(I) requested for New Drugs that were not in the available list to be informed to his office along with copy of approval/permission of drugs, including FDCs, new dosage form, new route of administration etc. approved by CDSCO (since 1951), to be submitted by 31st December 2019. We published the circular in the IDMA Bulletin issues dated 30th October and 30th November 2019 along with a Note requesting Members to avail of the opportunity and to ensure that their New Drugs are included in the list by providing the missing details as requested. Members were also informed about the opportunity by email on 26th November 2019.

Meetings and Interactions with Government

We had regular meetings and interactions with the Government during the year on important issues, especially of concern to our Members and also on industry's development plans. National President had led delegations for meetings with the following officials during the year and discussed some relevant issues such as:

- ***Dr P D Vaghela**, Secretary, Department of Pharmaceuticals (DOP) on various issues such as Price Revisions only from Prospective Batches, Proposed Pharma Pricing Policy, PTUAS, Clusters and Bulk Drug Parks etc.*
- ***Shri Navdeep Rinwa**, Joint Secretary (Policy), DOP on workshops to be conducted by CPCB with State Pollution Control Boards as discussed in the Task Force Meeting on APIs.*
- ***Dr Vinod Paul,** Member, NITI Aayog on the concerns of the industry and thanked him for retaining Trade Margins at 30%.*
- ***Ms Shubhra Singh**, Chairperson NPPA on Trade Margins, Incremental inventions and price implementation from prospective batches, WPI based revision to be continued for Scheduled formulations; products which were out of NLEM to be kept out of purview of WPI, retaining upto 10% per annum increase for non-scheduled drugs etc.*
- ***Ms Ritu Dhillon**, Member Secretary, NPPA on financial support through PTUAS for upgradation.*
- ***Mr Surendra Patel**, Deputy Secretary, Ministry of Labour & Employment on Draft Sales Promotion Employees Act.*
- ***Mr Piyush Srivastava**, Joint Secretary & Addl. Dev. Commissioner MSME on Credit Linked Capital Subsidy Scheme (CLCSS).*
- ***Mr Arun Singhal,** Addl. Secretary (Health) on Schedule M, technology upgradation of SMEs, PTUAS etc.*
- ***Dr Mandeep K Bhandari**, Joint Secretary (Health) on Amrit stores, substitution of prescribed medicines by pharmacist etc.*
- ***Mr Sudhansh Pant**, Joint Secretary (Health) on Central Medical Services Society (CMSS).*

Meetings with DCG(I) and Jt DCG(I)

We met Dr V G Somani, DCG(I) and Dr Eswara Reddy, Jt DCG(I) on 15th October 2019 at Delhi and discussed a few issues as below:

- ***Proposal to include "Marketer' under Drugs and Cosmetics Rules 2019**: Dr Somani informed that the process of notifying was almost complete and would be notified soon. The Marketer was expected to take responsibility of manufacturing the product along with the contract manufacturer. The Marketer would be held responsible as proposed only when the Marketer's name was printed on the label along with the manufacturer's and would not be held liable if his name was not included in the label.*
- ***Changing API in formulation, while retaining brand name**: Dr Somani informed that in such cases, adding a prefix or suffix to the brand name to distinguish it would be acceptable.*
- ***Approval of 83 FDCs** (under the 294 FDCs category): This matter is covered in detail in the Regulatory Affairs section.*

CDSCO Workshops for training manufacturers on data requirements

At the meeting of Forum of Associations on 24th June 2019, DCG(I) informed that CDSCO would be organizing Workshops at many pharma-centric cities for providing training to manufacturers on data requirements for drug product approval on recent amendments to Drugs & Cosmetics Rules. IDMA was entrusted with the task of organising the Workshops at a few venues. We successfully organised Workshops jointly with the Zonal CDSCOs and respective State FDAs at Ahmedabad on 17th August, Chennai on 31st August, and Mumbai & Kolkata on 7th September. About 2000 participants attended these Workshops. The details are covered in the Regulatory Affairs section.

Contract Manufacturing Conference

We organised a One-day Conference on "Creating Value through Partnerships" on 4th October 2019 at Mumbai. The Conference was a stupendous success and was well-attended with over 175 participants from about 90 pharmaceutical companies including important dignitaries, excellent speakers, moderators and panellists present at the Conference.

New key Appointments during the year

- ***Dr Venugopal Somani** as Drugs Controller General of India from 14th August 2019 replacing Dr Eswara Reddy.*
- ***Dr P D Vaghela,** IAS, as Secretary, Department of Pharmaceuticals from 24th July 2019 replacing Mr J P Prakash.*

Remembrance of Stalwarts

Mr N I Gandhi *(expired on 10th July 2019)*

Mr D B Mody *(expired on 28th August 2019)*

Mr Samprada Singh *(expired on 27th July 2019)*

Mr Amit Kumar Sen *(expired on 23rd March 2019)*

Mr Kapil Bhargava *(expired on 19th March 2019)*

Our Theme for 2020 - 2021

The world has recognized India as the preferred supplier of safe efficacious quality generics and increasingly looks towards India to provide quality affordable APIs and Pharmaceutical formulations. Hence our theme this year: **'Indian APIs and Formulations for Global Health care'.**

Our focussed and detailed representations were widely appreciated, and our Delhi office also provided active support in improving Public Relations in Delhi. Representations and achievements of IDMA, as also Circulars and Advisories on urgent matters were emailed immediately, and also regularly published in the weekly IDMA Bulletin for the benefit of members.

IDMA has come to be known as the leading industry-representative Association nationally as well as internationally, as we have actively participated in all Meetings, Seminars, Forums and Award functions. The visibility has been felt and experienced by one and all as we have always kept the interest of our Members in mind and addressed their queries very promptly.

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

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

Wishing you all a very Happy, Health and Prosperous 2020

Yours Sincerely,

Daara B Patel
Secretary-General

BULK DRUGS

Task Force meetings

IDMA continued to be Member of Task Force on API formed by Department of Pharmaceuticals (DOP), which was initiated last year. Third and fourth meetings of the Task Force were held in February and June 2019 respectively under the Chairmanship of Hon'ble Minister of State Shri Mansukh L Mandaviya. Issues relating to Environment Ministry and CPCB in working out some solutions to ease the burden of API manufacturers were discussed. Along with DOP, senior officials from Ministry of Commerce, Ministry of Health, DCG(I), CSIR etc were present. Unfortunately, in both meetings only a junior official from Ministry of Environment was present. We made a presentation highlighting the following: (i) some key APIs not manufactured in India; (ii) APIs recommended for increase in Import Duty; (iii) Intermediates recommended for reduction in Import Duty; (iv) Need for simplify some current procedures followed by Pollution Control Boards, which hinder growth of API Industry such as (a) long and tedious procedure for change in Product-Mix, and (b) long and expensive procedure for Environment Clearance for increasing production or adding new equipment etc. We suggested self-certification for change in product mix for APIs and intermediates. Shri P. Raghavendra Rao, Secretary, DoP requested Ministry of Environment that for minor changes there should not be any need for approvals. The Secretaryrequested Ministry of Environment to communicate all clarifications, such as one issued by CPCB to IDMA on pollution control measure to all SPCBs.

Meetings with CPCB

We met Shri S. P. Singh Parihar, Chairman, CPCB on 13th September 2019 and discussed some urgent issues such as need for providing flexibility to API manufacturers to make quick changes in product mix in order to adapt to constantly changing world demand, reasonable time limit to be fixed for permission for expansion, disproportionate punishment for simple contraventions etc. Following the Task Force meetings, Ministry of Environment had initiated a Workshop to be organised under the aegis of CPCB, but the same was postponed by them. Subsequently along with BDMA, we made a joint submission requesting for a meeting of industry and CPCB along with State PCBs of 8 important States, where there is significant bulk drug manufacturing. We also requested that other regulatory stakeholders such as DCG(I), DOP etc may also be invited to participate in this meeting. At the behest of Secretary, DoP, Chairman, CPCB agreed for such a meeting.

CPCB–SPCB-Industry Interactive Workshop on Environment Issues

A joint CPCB–SPCB-Industry Interactive Workshop was organised on 10th October by Shri S.P. Singh Parihar, (IAS) Chairman, CPCB with active participation of industry representatives and officials from CPCB, MoEF and SPCB from API-centric States Maharashtra, Telengana,

Andhra Pradesh, Gujarat, Punjab, Madhya Pradesh. Mr Navdeep Rinwa, Jt Sec, DoP was also present. CPCB made a presentation with their comments against each of the points raised in the IDMA-BDMA joint submission. Dr Sharad, Director, MoEF informed that a draft EIA notification 2019 had already been prepared, but due to two cases pending before Delhi High Court and Supreme Court, they were not able to release the notification. After detailed deliberations, certain actions were recommended by Chairman such as (a) to issue an advisory to all SPCBs to grant product change approvals within one month's time; (b) DoP was requested by the Chairman to suggest simplification of format of application form which currently asks for confidential process information unrelated to effluent treatment: (c) SPCBs to set up fast track mechanism for ZLD units. We subsequently submitted our comments on 29 October jointly with BDMA on the presentation made by CPCB. Furnishing of information to DoP is continuing to help them for preparing their recommendations to CPCB.

Meetings with MPCB and GPCB

We had meetings with Dr Bhushan Gagrani, IAS, Principal Secretary, Maharashtra, Mr. E. Ravendiran, IAS, Member Secretary, MPCB and Shri K C Mistry, Member Secretary, GPCB in February, May, July and September this year to seek solutions on easing environment regulations.

We also met Dr Pallavi Darade, Commissioner, FDA Maharashtra and the Minister of State for FDA, Maharashtra, Shri Jaykumar Rawalon 18th July and discussed issues of bulk drug industry in Maharashtra. The officials at Maharashtra Government were apprised of the issues and requested to work out solutions within the regulatory framework. In our discussions and submissions, we stressed that self-certification for change in product mix should be allowed and also quoted the example of Gujarat where GPCB has started giving product permission as general category "dyestuffs" instead of individual products. Similar treatment should be done for APIs and changes within the group category should be allowed.

Rise in Anti-Microbial Resistance

Department of Pharmaceuticals approached IDMA vide their letter dated 11th October 2019 on the subject of rise in Anti-Microbial Resistance (AMR) due to pharmaceutical pollution resulting in development of 'superbugs'. The CPCB had set up an expert Committee to draft standards for antibiotic residue and we had provided substantial inputs. DoP estimated that as of 2014, nearly 700,000 people lost their lives to resistant infections every year globally. At this rate, by 2050, AMR could cause an estimated 10 million deaths per year, and about US$ 100 trillion of the world's economic output could be lost if substantial efforts were not made to contain this threat. Further, it was estimated that India could bear a huge environmental load due to pharmaceutical pollution, as India along with China contributed almost 80 to 90 per cent of the world's antibiotic production. DoP requested manufacturers to sell and manufacture responsibly and take steps to remove antibiotic residue from their effluents as an initial step towards AMR containment.

Monitoring end-use of Dual-Use APIs

DCG(I) issued an OM dated 18-10-2019 informing that for Dual-use APIs, one-time NOC would be issued by CDSCO Zonal offices for one year to manufacturers importing such products for their own end use (other than medicinal use). The NOC would be based on written undertaking by the manufacturer justifying the quantity proposed for one year. This period would be further relaxed, if the data submitted and the operations carried out showed that it was for self-consumption for further manufacturing.

NOCs for manufacture of Unapproved drugs for Export

DCG(I) circular dated 2nd August 2019 informed that NOCs being granted by CDSCO for manufacture of Unapproved, Banned, New Drugs only for Exports would henceforth be issued by State Licensing Authorities under certain conditions. NOCs would be issued only against a valid Export Order.

Draft D&C Notification proposing QR Code for API packs

A draft notification [GSR 567 dated 8th August 2019) was issued under Drugs and Cosmetics Rules proposing that every API manufactured in India or imported into India would need to carry Quick Response code on its label to facilitate tracking and tracing. Details to be included in the QR Code was also specified. The issue is covered in detail under the Regulatory Affairs Section.

EMPLOYEE RELATIONS & DEVELOPMENT

Four Labour Codes issues by Government

Government of India initiated a new labour legislation to merge 44 labour laws under four Codes covering Wages; Industrial Relations; Social Security; and Occupational Safety, Health and Working Conditions respectively, by simplifying, amalgamating and rationalizing the relevant provisions of the existing Central Labour Laws. The Codes drafted by Ministry of Labour and Employment contain provisions relating to wage, social security, safety, health and grievance redressal mechanism, wage security, social security, occupational safety and decent working conditions to the workers etc.The laws related to social security, including the Employees' Provident Fund and Miscellaneous Provisions Act, Employees' State Insurance Corporation Act, Maternity Benefits Act, Building and Other Construction Workers Act and the Employees' Compensation Act are merged to create a single Code on Social Security. Several industrial safety and welfare laws such as the Factories Act, the Mines Act and the Dock Workers (Safety, Health and Welfare) Act, have been merged to create a single category as Code on Occupational Safety Health and Working Conditions. The Minimum Wages Act, the Payment of Wages Act, the Payment of Bonus Act, the Equal Remuneration Act and a few others have been merged under Code on Wages. Code on Industrial Relations combined Industrial Disputes Act, 1947, the Trade Unions Act, 1926, and the Industrial Employment (Standing Orders) Act, 1946.

Code on Wages Act and draft Rules 2019

The Code on Wages Bill 2019 was enacted on 8th August 2019. The Code merged four labour laws - the Payment of Wages Act of 1936, Minimum Wages Act of 1948, Payment of Bonus Act of 1965 and Equal Remuneration Act of 1976 into a single Code. The Code incorporated relevant provisions of the previous laws pertaining to workers' wages, equal remuneration for men and women, its payment and bonus. Draft Rules were released for comments by stakeholders.

WPs in Jharkhand, Patna, Chattisgarh, Tamil Nadu

Writ Petitions have been filed at High Courts of Jharkhand at Ranchi Chattisgarh and Madras (Tamil Nadu) this year seeking to quash the respective State Labour Department's notices for fixing of timings for Medical Representatives.The WP in Patna High Court was initiated in 2017 and is awaiting final hearing and judgement.

EXCISE & TAXATION

Clarifying treatment of Sales Promotion schemes under GST

We had regular interactions with NITI Aayog and GST Council seeking clarifications on GST implementation issues and ITC on sales promotion schemes such as free samples and bonus offers that are specific to pharma industry. CBIC released a Circular(No. 92 dated 7 March 2019) clarifying issues related to these schemes under GST. Applicability of GST and ITC for various kinds of free goods and offers were clarified by CBIC applicable to pharma industry as below:

(a) **Free Samples & Gifts:** We often provide Physician samples to medical practitioners without charging any consideration and gifts to stockists, dealers, medical practitioners etc. Industry does not avail ITC on goods disposed of by way of gift or free samples (as per Schedule I Section 17(5)(h) of GST Act) distributed without any consideration. CBIC clarified that ITC would not be available to the supplier on the inputs, input services and capital goods to the extent they were used in relation to the gifts or free samples distributed without any consideration. However, where the activity of distribution of gifts or free samples were within the scope of "supply" on account of the provisions contained in Schedule I of the said Act, the supplier would be eligible to avail of ITC.

(b) **Buy one get one free offer**: Promotional schemes such as Buy ten and get one or additional quantities for the same price etc, are part of the pharma business marketing practice. CBIC clarified that taxability of such supply would be dependent upon as to whether the supply was a composite supply or a mixed supply and the rate of tax would be determined as per the provisions of section 8 of the said Act. It was also clarified that ITC would be available to the supplier for the inputs, input services and capital goods used in relation to supply of goods or services or both as part of such offers. Further, in case of clubbing of two different products under a free scheme, the highest rate applicable amongst the two products would apply to the whole (being considered as a 'mixed supply').

(c) **Discounts including 'Buy more, save more' offers**: Our Industry offers staggered discount to customers (increase in discount rate with increase in purchase volume). Such discounts were established in terms of an agreement entered into or before the time of supply though not shown on the invoice as the actual quantum of such discounts gets determined after the supply has been effected and generally at the year end. CBIC clarified that discounts for sale by volume offered by the suppliers to customers (including staggered discounts under "Buy more, save more" scheme and post supply / volume discounts established before or at the time of supply) would be excluded to determine the value of supply provided they satisfied the parameters laid down in sub-section (3) of section 15 of the said Act, including the reversal of ITC by the recipient of the supply as was attributable to the discount on the basis of document(s) issued by the supplier. Further, the supplier would be entitled to avail the ITC for such inputs, input services and capital goods used in relation to the supply of goods or services or both on such discounts.

Union Budget 2019-20 – Recommendations

The Department of Revenue, Ministry of Finance invited IDMA to discuss our recommendations for revision in Direct and Indirect Taxes on 24th May 2019. Our recommendations submitted to the Ministry of Finance include the following key issues:

- Reduction in Tax Rates: Wherever there are same Four Digit HSN Code attracting the different rate considering the description of goods, rates have to be made at par and there should not be two slabs for the items falling under Four Digit based on different description.
- To amend the exclusion clause of input tax credit and allow the credit w.r.t. free samples and goods destroyed due to expiry so that the credit can be availed w.r.t. the input taxes.
- The distribution of credit should not be restricted to same month. The limit of availment is already in place and hence there should not be any further restriction w.r.t. distribution of credit. At most the restriction should be limited to period upto due date for filing annual return.
- Provision for refund of ITC against export to be aligned in line with refund of duty draw back wherein, basis the shipping bill, refund of ITC be processed at fixed rate to be determined based on the GST rate applicable to the goods exported.
- Unlike corporate tax rate, there is no roadmap available for reduction of the MAT rate which, currently is 18.5%. We proposed that the MAT rate should be reduced to half of the normal tax rate.
- Depreciation rate for all medical / surgical / pathological equipments including life - saving medical equipments be increased to 60%
- A weighted deduction of 200% of the amount spent on specified activities like investment in rural/semi-urban healthcare infrastructure.
- Existing provisions to be specifically clarified to allow weighted deduction in respect of expenditure incurred outside the R&D facility which are sometimes necessitated by the industry's business needs.

We also participated in the interactive meeting with Department of Revenue and made a presentation of our recommendations.

Pre-Budget 2020-21 Meeting

We participated in the Pre-Budget 2020-21 meeting organised by CBIC on 13th Dec 2019. Officials from CBDT and Trade Research Unit (Department of Revenue) also participated. We submitted our suggestions on Direct Taxes and Indirect Taxes and our recommendations were discussed in detail at the meeting.

Penalty for Non-compliance of CSR

CSR provisions were amended in July 2019 under the Companies Act with stricter penalties, including fines and jail terms, to companies not fulfilling their CSR requirements. The amendments had provisions to penalise companies allegedly violating the rules from Rs 50,000 up to Rs 25 lakh. Company officials were also liable to be jailed for up to three years for non-compliance of their CSR. A high-level Committee chaired by Shri Injeti Srinivas, Secretary, Ministry of Corporate Affairs submitted its Report to the Finance Minister in August 2019 recommending that non-compliance of CSR norms be made only a civil offence and moved to a penalty regime for non-compliance.

Corporate Tax Rate for domestic companies reduced to 22%

Hon'ble Minister of Finance Smt Nirmala Sitharaman announced a significant reduction in corporate tax rate for domestic companies from 30% to 22% on 20 September 2019. This was applicable to domestic companies not availing any exemptions or incentives. Companies which had availed the option would be exempted from the applicability of Minimum Alternate Tax (MAT). Companies which were willing to avail the existing exemptions/incentives and did not opt for the concessional rate, could avail this rate after the expiry of the tax holiday period. However, they would continue to be taxed at the pre-amended rate till the option was exercised. MAT at the reduced rate of 15% would be applicable to companies, which wished to avail the existing exemptions and incentives. Taking it further, new domestic companies incorporated on or after October 1, 2019 and engaged in production and its distribution and also those commencing manufacturing on or before March 31, 2023 would have an option to pay corporate tax rate at 15%, provided the company was not availing any exemption/ incentive.

KPMG presentation on Corporate Tax Amendments

As the changes and revisions announced by Hon'ble Minister had wide implications on the corporate sector, at our invitation, KPMG made a presentation on "Tax Ordinance 2019" on 20th November 2019 to our Members explaining the implications of the proposed amendments. KPMG also made a presentation on "WTO Trade Dispute on India's Export Subsidies" highlighting the possible repercussions of some WTO decisions against India. They replied to the large number

of queries raised by Members and also noted a few issues that would need to be addressed by Government in the Tax Reforms.

E-assessment Scheme, 2019 notified

CBDT notified E-Assessment procedure [vide Notification nos. 61 and 62 - S.O. 3264 and 3265 respectively both dated 12th September 2019)] giving effect to the Income Tax E-Assessment Scheme, 2019 for conducting faceless scrutiny assessment of Income Tax Returns. Henceforth, all communication with tax payers and among assessment centres etc was proposed to be purely electronic and digitally authenticated; and assessees would not be required to make personal appearance at centres. It was later informed that the scheme would be made mandatory from 1st April 2020.

GST Council Recommendations

GST Council in their 37th meeting on 20th September 2019 recommended relaxation in filing of annual returns for MSMEs for FY 2017-18 and FY 2018-19 by providing waiver of requirement of filing Form GSTR-9A for Composition Taxpayers for the said tax periods. Filing of Form GSTR-9 for those taxpayers, who were required to file the said return, but had aggregate turnover up to Rs. 2 crores were made optional for the said tax periods.

INDUSTRY INSTITUTES INTERACTION

Draft Guideline on "Sharing public-funded R & D Resources"

The Office of Principal Scientific Advisor to the Government of India forwarded us the draft guideline on "Sharing public-funded R & D Resources". This was proposed to be worked thru' an online national portal I-STEM (Indian Science Technology and Engineering facilities Map) that was set up to list all scientific, technical, analytical, research equipment, facilities etc procured with funds provided by Government of India and for agencies established by the Government of India which are available in academic and R & D organisations across the country. The objective of the online national network was to connect the research and researchers, speed up the R&D productivity and enhance the effectiveness of public investment and use of public infrastructure.

INTERNATIONAL TRADE & CUSTOMS

Meeting of Expert Committee on Track & Trace

Mr. Shyamal Misra, Joint Secretary, Commerce chaired a meeting of Expert Committee on Track & Trace on 10th April 2019 to discuss issues being faced by Pharma exporters in implementation of barcoding. We made a written submission highlighting our concerns such as:

- As the system of Parent Child Relationship was not workable due to several issues, it should not be made mandatory at all.
- Since India is an exporting country, Track and Trace may be made optional until an internationally acceptable harmonious system is evolved.
- DAVA Portal may be enabled to allow 2D barcode numbers or similar unique code numbers, without parent child relationship. This number or barcode printed on secondary packing could be verified for authenticity by patient or trade by logging onto the portal.
- The portal may be redesigned to accept only Tertiary codes for all exporters instead of aggregated data.

Track & Trace for Pharma Export Packs extended to 1 April 2020

DGFT issued a Public Notice [No. 16 dated 4th July 2019] extending the implementation of Track & Trace for pharma export packs from 1st July 2019 to 1 April 2020 for SSI and non-SSI manufactured drugs, with respect to maintaining parent-child relationship in package levels and uploading it on DAVA Portal.

Meeting on RCEP with Shri Piyush Goyal, Minister of C&I

Shri Piyush Goyal, Hon'ble Minister of Commerce and Industry held a stakeholders meeting in Mumbai on 22 July to discuss RCEP.The Minister informed that only tariff related issues would be discussed and our suggestions on Non-Tariff Barriers were submitted separately to Ministry of Commerce.

IPR

USTR report

USTR (United States Trade Representative) Annual Report for 2019 was released in April 2019 and India, as in earlier years, was placed in the "Priority Watch List" even for routine IPR and Regulatory issues. The usual negative comments on Compulsory Licence, Sec.3(d) (patentability criteria), protection against unfair commercial use (data exclusivity) and unauthorized disclosure (for marketing approval), was repeated in the 2019 Report. However, the 2019 Report had gone one step further and alleged that 55% of global seizures of counterfeit pharmaceuticals originated from India and was exported to Africa, Europe and USA. IDMA has strongly responded and refuted the allegations.

Negative allegations about Generic Drugs

Ms Katherine Eban, an investigative medical reporter on pharmaceuticals and public health in USA, had written a book 'Bottle of Lies' that alleged serious malpractices in manufacturing and documenting practices at some US FDA approved sites in India and questioned the quality of the

generic drugs manufactured in these plants. The author also made serious adverse comments about US FDA inspections and the inferences in the book were reportedly based on past information of select cases. We made a detailed submission to Department of Commerce on 4th June 2019 explaining our views on the book and the USTR report. Articles have been published in the newspapers which we have strongly refuted and challenged the allegations. We have also published a special coverage in *IDMA Bulletin* dated 14 June 2019 highlighting the myths and refuting the allegations.

NBA draft Notification - Guidelines on Access to Biological Resources

The National Biodiversity Authority published a draft notification on 'Guidelines on Access to Biological Resources and Associated Knowledge and Equitable Sharing of Benefits Regulations, 2019'. This followed the (Indian) Biodiversity Act, 2002 and Rules 2004. Research in Indian natural products and bio resources were reportedly adversely impacted as a result of the tight and impractical controls by NBA and State Boards.

Reduction in fees for SMEs for filing IPRs proposed

Ministry of Commerce and Industry proposed to reduce fees for various Intellectual Property Rights like patents and designs for MSMEs and startups to promote innovation. As per the proposal, fees for MSMEs and startups for filing of patent applications would be reduced to Rs 1,600 or Rs 1,750 from Rs 4,000 or Rs 4,400. For expedited examination, it would be Rs 8,000 instead of Rs 25,000 currently.

FDI Policy amended to include Contract Manufacturing

Department for Promotion of Industry and Internal Trade (DPIIT) issued a Press Note dated 18th September 2019 amending the FDI Policy of 2017. One key amendment was recognition of 'Contract Manufacturing'. The revised Policy recognised FDI in manufacturing sector under automatic route that may be either self-manufacturing by the investee entity or contract manufacturing in India through a legally tenable contract, whether on P to P or Principal to Agent basis.

A further (second) Biodiversity Guidelines for Benefit Sharing

Following our persistent efforts and representations, the revised "Guidelines on Access to Biological Resources and Associated Knowledge and Equitable Sharing of Benefits Regulations 2019" were released in December 2019 as a draft notification. Benefit sharing procedures, ratios and percentages have been substantially revised downwards to make the Act and Rules more user-friendly. Mode of benefit sharing in IPR (Patents) have also been revised. When patented products and processes based on Natural products are commercialized by Patentee, the rate has been lowered to 0.5% to 1.0%. When patented invention is licensed or assigned, the benefit sharing will be 2.0% to 5.0% of licensing fee received and 2.0% to 5.0% of royalty received. Similarly, the mode and rate of benefit sharing for transfer of research or material to overseas etc have also been revised and reduced. Criteria for benefit sharing for deposition

of novel microbial strains overseas, sharing of benefits between NBA/SBBs (State Biodiversity Boards) and benefit claimers have also been revised. Fair and equitable benefit sharing options (Annexure II), such as Monetary benefit sharing options, Non-monetary benefit sharing options have also been notified. The non-monetary benefit sharing options notified would be worth evaluating and pursuing by Natural product researchers, research institutions and Academic organisations.

Patent Amendment Rules, 2019 (GSR 663 dt 17 Sept 2019)

Provision for Expedited Examination in Form 18A (earlier subject to filing PCT Application with India as ISA) has now been liberalised. Women Applicants, small entities, start-ups, government institutions, PPH applicants on mutual acceptance basis are now eligible for Expedited Examination on payment of fees without any precondition. Only documents to prove eligibility in the category specified need to be filed for Expedited Examination.

DPIIT website and Mobile app for IPR

DPIIT (Department for Promotion of Industry and Internal Trade) launched Mobile App L2Pro India (**Learn to Protect, Secure and Maximize Your Innovation) on IPR through CIPAM-DPIIT in collaboration with Qualcomm and NLU, Delhi.**

Patent Prosecution Highway (PPH)

Consequent to responses to draft rules notified earlier, the Patent Rules have been amended with Cabinet approval for opening up the Patent Prosecution Highway (PPH). Pharmaceuticals, Chemicals, Biotechnology and related areas are not covered by PPH [in view of special enabling provisions in the (Indian) Patents Act, 1970].

Intellectual Property Appellate Board (IPAB)

IDMA has represented strongly about the non-functioning status of IPAB, where the posts of Chairman, Vice Chairman, Technical Member, Judicial Member are all lying vacant indefinitely. While a status report on actions being taken is received from DPIIT, the IPAB continues to be non-functional.

MARKETING

Marketing Conference 'Growing Brands to Level Next' at Mumbai and Kolkata

We organised a One-Day Marketing and Sales Conference 2019 on the theme 'Growing Brands to Level Next' on 10th May, 2019 at Mumbai. The galaxy of speakers included Mr Sudarshan Jain speaking on "Growing Business is Building Brands", Mr Salil Kallianpur on "Using digital to build a better customer engagement strategy" and others. The Conference was also organised at

Kolkata on 21st September 2019. The Conference provided excellent take aways with the speakers focussing on taking marketing to next level and using Digital Technology platforms for connecting to people.

Undertaking of Ownership of Brand name for Marketing

The Ministry of Health and Family Welfare published a draft notification (GSR 152 dated 26th February 2019) proposing a condition for grant or renewal of licence for all pharmaceutical products. The condition required that, for marketing a drug under a brand name / trade name, the applicant would be required to furnish an undertaking to the Licensing Authority. A gazette notification was issued later [vide GSR 828 dated 6 Nov 2019] to provide the Uundertaking and a new Form 51 introduced for the Marketer to sign an undertaking of Ownership of Brand name. This matter is covered in detail in the Regulatory Affairs section.

Proposed inclusion of 'Marketer' in D&C Rules

A draft notification [GSR 447 dated 24 June 2019] was issued to define 'Marketer' under Drugs and Cosmetics Rules to make the 'Marketer' also responsible, along with the manufacturer, for ensuring quality and regulatory compliances of the marketed drug. We made a detailed submission on 24 July 2019 highlighting the legal aspects and impact on cost and availability of drugs. This matter is covered in detail in the Regulatory Affairs section.

MSME

Specified Companies (Furnishing of information about payment to micro and small enterprise suppliers) Order, 2019

The Ministry of Micro Small and Medium Enterprises had issued a notification last year [S.O. 5622(E),dated 2nd November, 2018] directing all companies who get supplies of goods or services from MSMEs and whose payments to micro and small enterprise suppliers exceed forty five days from the date of acceptance or the date of deemed acceptance of the goods or services as per the provisions of the MSMED Act, 2006 to submit a half yearly return to the Ministry of Corporate Affairs (MCA). Following this, MCA issued a notification [SO 368 dated 22nd January 2019] specifying that all companies who purchase goods or avail services from MSMEs and whose payment to such suppliers have exceeded 45 days shall submit a half yearly return to the MCA stating the outstanding amount and the reasons for delay. The accepted practice in the pharmaceutical industry was a timeline of 90 days and having to make payments within 45 days could disrupt the cycle, though MSMEs would benefit receiving payments within 45 days.

Reintroduction of CLCSS

We attended a meeting organised by Development Commissioner (MSME), Ministry of Micro, Small & Medium Enterprises on 19th March 2019 at Mumbai. About 25 Associations were

represented at the meeting. The Ministry of MSME proposed reintroduction of CLCSS (Credit Linked Capital Subsidy Scheme). The revised CLCSS would facilitate technology up-gradation in Micro and Small enterprises by providing an upfront capital subsidy of 15% (on institutional finance of upto Rs 1 crore availed by them) for induction of well-established and improved technology.

MEMBERSHIP & CONSTITUTION

Continued Growth of Membership

This year the Membership at the year-end stood at 1042. We were involved in bringing more Members to the IDMA fold so that they benefit by the activities of the Association. During the year, **85 New Members** were inducted namely, 59 Principal Members, 20 Associate Company Members, 3 Corporate Members and 3 Associate Academic Members, increasing the Membership to 1106. But as 64 Members had not renewed their Membership for more than a year despite repeated follow-ups, their Membership was discontinued. **Now the IDMA Membership strength is at 1042 Members at the year end.**

NDPS

Meeting with DG, DRI and Joint training Programs

We met various officials concerning NDPS matters between 6th to 8th February 2019. In our meeting with the Narcotics Commissioner we proposed that there should be a periodic interaction between CBN and Industry/Trade to discuss issues from both ends. He agreed to the same. At our meeting with Mr. D P Dash, Director General, DRI (Directorate of Revenue Intelligence) Ministry of Finance, we presented to him various policy initiatives by IDMA over the last 8 years and also the pending pain points. We proposed that DRI being one of the enforcement agencies involved in NDPS cases, Industry interaction with DRI may be increased. A letter was sent to DRI on 30th May 2019 proposing periodic half yearly interaction between IDMA and DRI and also Joint training programs.

Meetings with NCB

We met Mr.Rajesh NandanShrivastava, DDG, NCB (Operations) and Mr. Abhay, DG, NCB and raised the issue of misdirected investigations and our request for issuing a Standing Order with respect to Procedures of Investigation, under the NDPS Act, pertaining to licensed entities, so that harassment of legal entities could be mitigated.DG, NCB and DDG (Operations) assured to look into Industry and Trade concerns in the Procedure for Investigations. Subesquently, it is understood that NCB has issued internal guidelines on Procedure for Investigations for controlled substances.

Intimation of Yellow, Green and Red list of substances under International Control

NCB organised a meeting on 26th February 2019 at Delhi to understand Industry issues and also how Industry and NCB could work together to mitigate diversion from legal to illegal channels. They requested that IDMA members be made aware of the list of substances that were controlled internationally under 3 categories, namely Yellow list of substances – Narcotic substances, Green list of substances – Psychotropic substances, Red list of substances – Precursor chemicals / Controlled substances. Also Ketamine, Khat, Tramadol and other substances as Psychotropic substances under NDPS Act, 1985. As requested by the NCB, we issued a circular to all Members by email on 5 March 2019 requesting them to ensure that all necessary licenses or authorisations are in place while dealing with such substances to ensure compliance.

Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Amendment Order, 2019

The amendment vide notification GSR 779 dated 14th Oct 2019 makes it mandatory for sale or distribution or mediate in the sale/purchase through website, social media or in any other manner of any controlled substance included in Schedule-A, to register and obtain a unique registration number in Form-A, issued by the Zonal Director of the Narcotics Control Bureau. Such entities shall file quarterly return in Form-E, Form-F, or Form-L, as the case may be, to the concerned Zonal Director of the Narcotics Control Bureau having jurisdiction over the area.

NUTRACEUTICAL

FSSAI Circular for licensing requirements

FSSAI issued a Circular dated 1st July 2019 proposing to launch a special drive to address four types of non-compliances by FBOs such as (1) FBOs who have obtained registration certificate despite being required to obtain a license, (2) FBOs continuing food business with expired License/ without License, (3) FBOs who have obtained fresh License/Registration instead of renewing previous one to avoid penalty and (4) FBOs manufacturing/processing food products which are not endorsed in the license. We made a submission dated 14th August 2019 highlighting our concerns.

Restriction on approval of Methylcobalamin in Gujarat

FDCA, Gujarat issued a circular dated 11th June 2019 banning Methylcobalamin, stating that it was not approved under the various schedules of the FSS Regulations 2016 for Nutraceuticals and other food products. FSSAI Advisory dated 29th December 2017 provided for implementation of the FSS Regulations and stipulated that “suitable esters, derivatives and salts of vitamins and salts and chelates of mineral may be used”. It appeared that licenses under FSSA for Methylcobalamin containing products were issued by almost all states except Gujarat.

PRICING/CONSUMER AFFAIRS

Public Procurement Policy - Revisions for Pharma Sector

DOP brought in cheer to the Indian Pharma Industry on the 1st January 2019, notifying that all Government purchase orders of medicines would need a minimum local content and Phased Manufacturing Program as specified from 75% in 2018-19 to 90% by 2023-25. This would boost the 'Make in India' vision of our Government. DOP subsequently issued an order dated 14th January 2019 that the primary pack procured under Public Procurement Policy (PPP) would need to be barcoded with various details including MRP, special storage conditions etc. along with details of manufacturer, manufacturing date and expiry date etc. DOP later revised the implementation date to April 2020 vide an OM dated 1st February 2019, specifying that all pharma packs supplied under PPP and also sold in retail would need to carry a QR code.

DOP Forum of Associations

Department of Pharmaceuticals informed us vide a letter dated 14th August 2019 that they had set up a Forum of Associations to discuss issues concerning National Pharma Pricing Policy, DPCO 2013 and NPPA. We had already conveyed our suggestions to Government on proposed National Pharma Pricing Policy earlier. We requested that all pharma products priced at less than Rs 5 per unit be kept out of price control. Also all price revisions be made prospective from next batch only which would ensure timely compliance from industry and trade. The 1st meeting of the FOPA was held on 23rd August 2019 chaired by Dr P D Vaghela, Secretary, DOP. Ms Shubra Singh, Chairperson, NPPA, Member Secretary, NPPA and other officials from DOP were also present. We informed that we looked forward to a stable policy and requested that incremental innovations like ER, SR, NDDS, nano drugs etc be given separate pricing and should not be clubbed along with conventional preparations for fixing of price.

DPCO 2013 Amendments

DOP vide S.O. 39 (E) dated 3rd January 2019 notified some amendments to DPCO 2013, though the draft was not circulated for discussion among stakeholders. The amendments included regularising sources for market data, amending provisions for drugs patented in India to be out of purview of DPCO etc. We made a representation to Secretary, DOP on 29 January 2019 that, though regularising sources for market data was expected, the practice of referring to six months' old data as reference for fixing prices would need to be persisted with and not consider data randomly for any month. Amending provisions for drugs patented in India to be out of purview of DPCO was a matter of concern as it ran against the government's 'Make in India' policy and discouraged Indian firms from developing and producing patented drugs. Allowing Orphan drugs to be marketed freely could induce more drugs in the market. Para 32 (i) of DPCO 2013 was apparently amended to exempt a manufacturer producing a new drug patented under the Indian Patent Act for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. This appeared to be more in favour of MNCs as the need to manufacture the drug in

India through R&D was removed. Patent life could get extended beyond 20 years and also there would be no control on prices.

NLEM revision

The first Stakeholders National Consultation Meeting (SNCM) for revision of NLEM 2015 was held on 25th July 2019 at Delhi. As this was the first meeting, we made a brief preliminary submission requesting for appropriate caution while revising/adding formulations in NLEM. In our submission, we emphasised that 'Essentiality' should be the main criterion for inclusion in the NLEM and not the market size, sales data or span of control. We also requested the Committee to share the proposed NLEM under revision to provide our suggestions for inclusion and also recommend deletion of some formulations in the current list which are no longer considered essential. Prof Balram Bhargava, Chairman SNCM and Secretary DHR & Director General ICMR chaired the meeting. Prof Bhargava informed that the Committee would meet every six months and would make its recommendations to another Committee for deciding the drugs to be brought under price control. The 2nd meeting was held on 4th Nov 2019 in New Delhi and we raised the following key points for discussion:

- Essentiality in the Indian context should be the main criterion for inclusion in the NLEM and not market size.
- Specific strengths and dosages recommended by doctors only should be included in the NLEM.
- Proposed NLEM under revision may be shared with us so that we can provide suggestions.

The Committee agreed that only essentiality in the Indian context would be considered. Availability, adequacy, quality, dosage and price will determine essentiality, However, we must ensure that all essential medicines are affordable, whether under price control or not. They requested that the industry should prepare the list of drugs with specific strengths and dosages to be included or excluded in NLEM 2019 along with evidence and data for the drugs they want included or deleted in NLEM 2019.

Proposed cap on Trade Margins

Government was proposing to cap Trade Margins for branded generics at 30% at first Point of Sale for non-scheduled formulations (10% for wholesalers and 20% for retailers). We made an urgent submission to Dr Vinod Paul, NITI Aayog on 21nd February 2019 with calculations that, if margins were to be notified at first Point of Sale, then it would need to be 38.89%, as industry calculated MRP top down (MRP to PTS) whereas trade calculated it from PTS to MRP. Hence the disparity in calculations.

NPPA later issued a notification (SO. 1041(E) dated 27th February 2019) that the Government had undertaken price control through a 'Trade Margin Rationalisation Approach' due to the high trade margin in sale of drugs. And in order to bring in regulation of drugs in the 'non-scheduled' segment, Government had undertaken a Pilot for Proof of Concept by capping prices of select Anti-Cancer drugs, identified by the Ministry of Health & Family Welfare as being essential for the treatment. Out of 376 medicines listed in NLEM, 59 drugs were already under the category of Anti-neoplastic/immunosuppressive, Hormones & Antihormones and medicines used for palliative care and were price-controlled through DPCO 2013. A further 42 drugs were notified for price control under para 19. A cap on trade margin of 30% was set and manufacturers were directed to fix their retail price based on price at first point of sale and the information to be provided by 6th March 2019 in a specified format, with PTS sale price in June 2018 as benchmark. Based on data received by NPPA till 11th March, they released a list of 463 anti-cancer drugs identified by brand names with revised MRPs. Though the Trade Margins were set at 30%, the formula for working out the revised price from PTS allowed for 42% margin, as per industry calculations. Also, cancer drugs were sold directly to hospitals and invariably the MRP was set as requested by the hospitals.

WPI for 2018 notified by NPPA

NPPA issued an OM dated 20th March 2019 notifying annual change in Wholesale Price Index (WPI) for the year 2018 as 4.2662%.

Proposed Revision of WPI

Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry was preparing a revised list of pharmaceuticals for providing weightage in Wholesale Price Index (WPI) and requested for our inputs and suggestions. Though some pharmaceuticals were included in the earlier WPIs, the Department was proposing to include a detailed list of 265 pharmaceuticals and therapies, as also a few medicinal preparations, herbals etc. A consultative meeting was also held on 24th April 2019 on this matter.

DOP proposal for One-Time Amnesty

Department of Pharmaceuticals (DOP) sent us a letter dated 13th March 2019 informing that, following representations of IDMA and IPA dated 07-04-2015 and 20-06-2018, they were working on a draft Special One-Time Settlement (SOTS) Scheme for Overcharging Cases under DPCO, 1979, DPCO, 1987 and DPCO, 1995. The letter also stated that there were 666 cases pending for a long time, though the outstanding amounts mentioned in the letter were not clear. DOP offered to waive off interest if the principal amounts were paid by the companies. DOP sought specific proposals from IDMA and IPA with defined terms and conditions of SOTS Scheme and also whether IDMA or IPA could ensure, after the payment of outstanding dues that there would be no legal case. We submitted a reply to DOP on 22nd April that the outstanding dues of various companies put up on the NPPA website were mainly due to discrepancies arising from wrong computation of prices of bulk drugs and formulations under the DPCOs. As each case had its

own merits and demerits and the issue involved in each case was dissimilar, it would not be feasible for the Association to suggest any collective solution or formula on behalf of individual companies.

Certain Clauses in PTUAS

We made a submission to Shri Navdeep Rinwa, Jt Secretary, DOP on 27th June 2019 informing our concerns on the conditions for implementation of Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS). A provision under the 'Guidelines for Implementation' mandated export activities for availing of loan under PTUAS and we requested for removal of this restricting clause, as many SMEs would be interested in improving their manufacturing standards and quality of products for the domestic market. We also requested that the moratorium period be extended to at least 5 years for API and Pharmaceutical manufacturing industries. At the FOPA meeting reported earlier, we informed that PTUAS was planned with interest subvention of 6% and SMEs were waiting for its implementation. We requested that the amount of Rs 4 crores would not be adequate and would need to be raised to Rs 10 Crores.

Meeting with DOP, NPPA and NITI Aayog

In an effort to get our issues as mentioned above addressed and resolved, we had regular meetings with Dr Vinod Paul, Member, NITI Aayog, Dr P D Vaghela, Secretary, DOP, Mrs Shubhra Singh, Chairperson, NPPA and Ms Ritu Dhillon, Member Secretary, NPPA and other officials during the year. Details are covered under the General section.

NPPA order for 50% increase to certain formulations under Para 19 of DPCO 2013

At the 71st meeting of NPPA held on 9th December 2019, NPPA noted that they had been receiving applications for upward price revision under para 19 of DPCO, 2013 since last two years citing various reasons like increase in API cost, increase in cost of production, exchange rates etc resulting in unviability in sustainable production and marketing of the drugs. The Standing Committee on Affordable Medicines and Health Products (SCAMHP) under NITI Aayog recommended that there was a need to revisit the prices of 12 formulations presented to it for upward price revision under para 19 of DPCO 2013 by allowing one-time 50% increase from the present ceiling price. NPPA included another 9 formulations, as recommended by NITI Aayog for upward price revision. NPPA noted that the 21 scheduled formulations being considered for upward price revision under para 19 of DPCO 2013 were low priced drugs and were under repeated price control. Most of these drugs were being used as first line of treatment and as they are crucial to the public health program of the country. Many companies had applied for discontinuation of the product on account of unviability. NPPA issued a notification on 13th December 2019 for one time price increase of 50% for these 21 formulations from the present ceiling price.

PUBLICATIONS

56th Indian Drugs Annual Day Celebrations

Indian Drugs Journaland the IDMA IPR Committee and jointly organised the Indian Drugs 56th Annual Day Celebrations along with the Indian Education Society (IES) on 22nd March 2019 at their campus at Bandra, Mumbai. Over 120 delegates including Editorial Board members and Reviewers of Indian Drugs, and from IDMA, Past Presidents, Executive Committee members, Quality Management Technical Committee Members, etc participated. Also present were Principals of various Pharmacy Colleges, CEOs and heads of corporations and other invitees. The theme of the Celebrations was 'Innovation in Pharma Research: An Indian Perspective'. The Chief Guest was Dr Ahmed Kamal, FNASc, FAPSc, FRSC, Pro Vice Chancellor Jamia Hamdard University. The Guests of Honour were Dr Madhu Dikshit, FNA, FNASc, FASc, FAMS, JC Bose National Fellow, THSTI National Chair, NCR Biotech Science Cluster and Dr Premnath V., Head, NCL Innovations National Chemical Laboratory, Pune. The honoured Guests also included eminent personalities such as Mr Ajit Singh, Chairman, ACG Associated Capsules Pvt Ltd., Mr Sudarshan Jain, Senior Partner, APAX Partners, Dr Dinesh Harsolekar, Director, IES MCRC etc. The event was sponsored by Sai Mirra, Gufic Bioscience, Lab link and Chromachemie Laboratory Pvt Ltd.

57th Annual Publication

The 57th Annual Publication 2018 was a very special edition with the theme 'Indian Pharmaceuticals Nation's Pride'. The Message from the National President Mr Deepnath Roy Chowdhury and the 'Foreword' by Dr Gopakumar G Nair, Editor, IDMA Publications set the tone with an expert review of the contributions of the Indian Pharmaceuticals Industry in saving lives, preventive treatments, medications, immunizations etcwith one in three patients globally consuming medicines 'Made in India' and one in every two patients receiving treatments and immunization using vaccines 'Made in India'. This compendium contained data on New Drugs approved for marketing from the year 1988 till date, Health Statistics of India, and various other useful data and information. The Publication was released on the occasion of the 55th Annual Celebrations of the Association held on 20th January 2018 at Mumbai and was well received by all as a useful reference book.

IDMA Bulletin

IDMA Bulletin was published every week on time. Through this publication up-to-date information and data was disseminated on developments in the drug industry to all our members & subscribers. Also the activities of the Association, the various Seminars and Workshops organised by Mumbai Secretariat as also by the State Boards, representations made to various Ministries and Departments, and all other important developments were regularly reported. IDMA Bulletin, in its 50thyear of publication, continued to be the only weekly Bulletin of the Pharmaceutical Industry.

Indian Drugs

With the continued success of the Indian Drugswebsite: www.indiandrugsonline.org research papers, review articles and short notes were being received only online at the portal. The portal enabled authors to submit their original research papers online and the referees to review them online thus eliminating the need for hard copies and also speeded up the review process. The Indian Drugs journal continued to be printed and the published journal was also made available on the website for reference for subscribers. 'Indian Drugs' is now listed in the 'A' list of Journals approved by University Grants Commission (UGC) for Career Advancement Scheme (CAS) and Appointment of University Teachers. The Indian Drugs journal in its 56th year, was abstracted by SCOPUS, INTERNATIONAL PHARMACEUTICAL ABSTRACTS, OCLC WORLDCAT, JOURNAL GUIDE, SCIENCE LIBRARY INDEX, EMBASE, GENAMICS JOURNALSEEK, SCIMAGO, TDNeT, DRJI, INFOTRIEVE CCC, INDEX COPERNICUS, EBSCO, CITEFACTOR, ELECTRONIC JOURNALS LIBRARY, SHERPA/ROMEO, RESEARCHBIB, INDIAN CITATION INDEX, i-JOURNALS, i-FOCUS, I-FUTURE.

IDMA ACG-SCITECH Research Paper Award 2018

Beginning from this year, M/s ACG Worldwide was pleased to support the Indian Drugs Best Paper Awards. The best paper in each discipline published from January to December 2018 was selected by the judges. The Award now known as IDMA ACG-SCITECH Research Paper Award in the form of a citation, plaque and a cash award of Rs. 5000 in each discipline and the Best Review Article Award in the form of a citation, plaque and special cash award of Rs. 7500 were awarded to the authors of the Best Papers and Review Article. The details of the Awards are reproduced in the following pages.

Editorial Committee Meetings

A meeting of Editorial Committee members was held on 11th May 2019 to review the operations of the publications and suggest improvements to be made. The meeting was attended by the Editor, Associate Editors and Consulting Editor, Secretary General and IDMA Secretariat members assisting in the Publications. It was decided to induct young Members who could contribute to the Editorial Board and Editorial Advisory Board in place of members who are currently not active or unable to contribute due to other preoccupations. It was decided to inform the subscribers their user name and password so as to enable them to access the all published papers in Indian Drugs through the website www.indiandrugs.online.org. It was also decided one issue of Indian drugs per annum shall be made available on our online website for free of cost. An editorial meeting was also held on 9th November 2019 to induct four to five editorial assistant to screen manuscripts received through our online journal system.

A meeting was held on 13th August 2019 with E-live pages, the online developer of Indian Drugs to review the working of the online site www.indiandrugsonline.org and to review problems associated with the current running of the website.

QUALITY MANAGEMENT & TECHNICAL

21st IDMA-APA PAC 2019

Our flagship event, the 21st IDMA-APA Pharmaceutical Analysts Convention (PAC) 2019 was held on 24th and 25th May 2019 at Mumbai on the theme "Technology - The Game Changer". Mr. Annaswamy Vaidheesh, VP South Asia & MD, GSK and President of OPPI was the Chief Guest. Dr. P.B.N. Prasad, Deputy Drugs Controller (India), West Zone, Mumbai and Dr. Rubina Bose, Deputy Drugs Controller (India), West Zone, Mumbai were Special Guests of Honour. Technical Seasons and Breakout Sessions were also held. The Convention was well-attended with participation of over 225 delegates from more than 55 pharmaceutical companies. Delegates included professionals and experts from various disciplines such as Pharma Analysis, Quality Control, Quality Assurance, Regulatory, Production, R & D and many others from Academia, Marketing, Media etc. Participants included IDMA Executive Committee Members and Officials from IPC, CDSCO, MbPT, USP etc. The event was supported by over 22 companies.

The 21st IDMA-APA-PAC 2019 Souvenir and the Technical Document "IDMA – APA Technical Document on Quality 4.0 Digital Technology of the Future" were formally released. The 'IDMA-APA PAC Young Pharmaceutical Analyst Award 2019' was awarded to Mr. Vishal Madhukar Nagare, Senior Officer, Q. C. ,Glenmark Pharmaceutical Ltd, Nashik and the 21st IDMA-APA PAC Prof. Dr. R T Sane Outstanding Pharmaceutical Analyst Award 2019' was presented to Dr. Girish R. Valiyare, Director, Technical Services and Business Development in Raptakos, Brett & Co. Ltd, for their continued contribution to quality excellence and future potential in pharma industry.

Excellent presentations were made at the Technical Sessions by expert such as Dr.Ajit Kanetkar, Technical Advisor, ACG Worldwide presentation on, "Technology in Drug Development"; Mr A V Kiran, Head, Formulation Development, Innovation & Manufacturing Excellence Function, Sanofi-Synthelabo (I) Pvt. Ltd. presentation on "Novel Products"; Dr. Vinod Kumar Kansal, President R&D, Amoli Organics Ltd., presentation on, "Darker side of the Technology - A game changer"; Dr S G Belapure, Sr. Technical Advisor, IPA & Former MD, Zydus Hospira Oncology Pvt Ltd., presentation on, "Technological Advances in Manufacturing"; Mr. Vilas Dholye, Consultant presentation on, "Manufacturing Execution System (MES) : Challenges"; Dr. Ranjana Pathak, President-Global Quality, Medical Affairs and Pharmacovigilance, CIPLA presentation on "Technological Challenges In Quality Assurance"; Dr. Mrunal Jaywant, Sr. Director R&D, USP India presentation on "Technology Advances In QC - USP Perspective"; Ms. Sireesha Yadlapalli, Sr. Director, Strategic Marketing and External Affairs, USP-India presentation on "Technological advances in capability-building"; Dr Srinivas Malladi, Chief Scientific Officer, Chromachemie Laboratory Pvt Ltd presentation on "Frontiers in Impurity Synthesis and Characterization"; Mr Sumanth Chinta, Head – Presales, Caliber Technologies presentation on "Quality Focus in Pharma 4.0 ERA"; Dr.Parizad Elchidana, Principal Technical Consultant – Pharma, ACG presentation on "Regulatory challenges in new technology adoption"; Mr. Anurag Kaushik, Head Product Management Function, ACG Engineering, presentation on "Integrating technology to Optimize Overall Equipment Efficiency": Mr Kalpesh

Vaghela, CEO Infra Control Systems presentation on "cGxPExcellence through Automation"; Mr Venkanna Chowdary Manne, Managing Director, Ample Logic, presentation on "Digitalization in Pharma with Intelligent Systems"; Ms. Vanita Khatter, Head – Professional Services, UL INDIA, presentation on "Role of Learning Management Technology in Analyst Qualification"; Dr Ajit Datar, Advisor, Shimadzu, presentation on "Mass Spectrometry- The Game Changer". Mr Sanjay Sonar, Subject Matter Expert (Traceability Solutions) Optel Group, India, presentation on "End-to-End (E2E) Traceability: Leveraging digitization, serialization & disruption" etc.

Four break out sessions were held on Day Two of the Convention. The delegates were divided into 4 groups, with a Thought Leader directing deliberations in each group. Each group elected a member to take down all the key points from the session and create a presentation, which was then delivered by a representative delegate on behalf of the Group. The Breakout Session 1 was on "Product Development Technology":Thought Leader: Dr. Shailesh Nagarsenkar Moderator: Dr Uday Shetty, Group Leader Mr. M. K. Thinakar Krishna presented the summary. Breakout Session 2 was on "Manufacturing Technology": Thought Leader: Dr Satish Desai Moderator: Shri. Kaushik Desai, Group Leader Mr. Rajesh Kumar Presented the summary. Breakout Session 3 was on "Quality Technology": Thought Leader: Dr Gaurav Pathak Moderator: Shri. R. Raghunandanan, Group Leader Mr. Dharamvir Singh presented the summary. Breakout Session 4 was on "Regulatory Technology": Thought Leader: Dr Nilesh Gandhi Moderator: Ms Meena Shah, Group Leader Ms. Ishwari G. Karatagi Presented the summary.

IP Addendum 2019 implementation date extended

Following our submission to IPC, the implementation date of IP Addendum 2019 was extended by 3 months to 31st December 2019. This Addendum 2019 includes 62 new monographs and more than 220 revised monographs.

REGULATORY AFFAIRS

Proposed revision of Schedule M

Ministry of Health and Family Welfare had released a draft notification on 5th October 2018 seeking to revise and upgrade Schedule M under Drugs and Cosmetics Rules. The objective of this amendment appeared to be getting India ready for acquiring PIC/S Membership and thus the proposal included very major and to Schedule M based on WHO and PIC/s Guidelines.

A new section of Pharmaceutical Quality System (PQS) was introduced right at the beginning of the Schedule specifying ultimate responsibility on senior management for the PQS, besides additional requirements of adoption of Risk-based approach was indicated in the proposed Schedule. Phytopharmaceuticals was introduced for the first time in Schedule M.

Our long standing request to de-link restriction of API shelf life in determining the shelf life of the formulation was accepted, though the wordings appear to be incomplete.

We made a detailed submission on 17th January 2019 in two parts. The first part included detailed comparison between Schedule M that is mandatory in nature and WHO and EU GMP Requirements, that are in the nature of guidelines. Adoption of these guidelines in the Schedule will make them mandatory and will restrict the manufacturers the flexibility available for implementation of these guidelines based on the nature and scale of operations by adopting a risk-based approach.

In the second part as enclosure, we provided para-wise comments on the proposed clauses. We highlighted that by incorporating the WHO and PIC/s Guidances as Rules, manufacturers would be at a greater risk of being penalized for minor discrepancies, which would otherwise be acceptable without impacting the quality of the product. We requested that the proposed revision be revisited to include in Schedule M only relevant and specific additional requirements based on WHO Guidelines and EU systems and rest of the requirements included in Schedule M as Appendices, such as PQS and other additions be issue as Guidelines.

No brackets for FDCs in labels

With regular interactions with officials at Department of Health and CDSCO, especially with former DCG(I) Dr Eswara Reddy, and our submissions, the Ministry of Health and Family Welfare extended implementation of amendments to labelling on voluntary basis till 31th March 2019 and thereafter as mandatory. This amendment allowed manufacturers to switch over to new requirements voluntarily in a phased manner based on inventories of packaging materials.

The Ministry issued Gazette notification [GSR 205 dated 8th March 2019] eliminating the need to include brackets to brand names for FDCs of 3 drugs or more on labels under Rule 96 of D&C Rules. DTAB in their 81st meeting on 29th November 2018 had accepted IDMA's suggestion for omitting the brackets for FDCs of three or more drugs as proposed earlier, as it did not provide any additional benefit, and could be a violation of Trademark Rules. The Ministry had earlier issued a draft notification (GSR 88 dated 4th February 2019) omitting the words ''in brackets'' in Rule 96 of Drugs and Cosmetics Rules.

Guidelines on Action to be taken on NSQ drugs

Former DCG(I) Dr Eswara Reddy had informed us in our meetings that they had identified 44 tests where failures would not mean Not of Standard Quality (NSQ) and there would be no prosecution of such cases and offenses would be compounded, with a provision for appeal. We requested DCG(I) that there was an urgent need to define NSQ clearly. In our meeting with Shri J P Nadda, Hon'ble Minister of Health and Family Welfare in March last year, he had advised the Regulators that NSQ Guidelines be made part of Rules so that discretionary powers were reduced to a minimum. DTAB had also recommended that, as the guidelines were not statutory and their implementation varied from State to State, these NSQ drugs would need to be declared under different categories for taking regulatory action by incorporating the draft Rules as Schedule K1 to the Drugs and Cosmetic Rules.

80 FDCs banned from 294 FDCs list

From the list of 294 FDCs issued in 2007, 80 FDCs were banned by notifications on 11th January 2019. Earlier 49 FDCs were identified for Clinical Trials and PMS studies. 17 more FDCs were identified for which data provided by the manufacturer was considered inadequate to prove its rationality, safety and efficacy. 83 FDCs from the list of 294 FDCs were cleared last year for continued manufacture and marketing. The DCG(I) issued a Circular dated 27th February 2019 notifying procedure to be followed for regularisation of these 83 FDCs declared as rational by DTAB. As only 4 months were provided and 6 months' stability data was required to be provided, we made a submission on 8th July 2019 for an extension of 4 months more for submitting data.

Regularisation fees for FDCs

DCG(I) as reported earlier had issued a circular on 27th Feb 2019. The circular also informed that manufacturers holding license from SLAs for the 83 FDCs declared as rational (from the list of 294 FDCs) could submit their applications by paying fees of Rs 15,000 to CDSCO and obtain license from State SLAs. Dr V G Somani, DCG(I) issued a Notice dated 19th August 2019 that applications could still be made by 2nd December 2019 under New Drugs and Clinical Trials Rules 2019, which meant payment of fees of Rs 2 lakhs per application as New Drug. We made a submission to DCG(I) on 6th November 2019 requesting that fees of Rs 15,000/- may be continued for all FDCs approved prior to the notification of New Drugs and Clinical Trials Rules 2019 under GSR 227 dated 19th March 2019. DCG(I) issued a notice on 5th December 2019 informing that MSMEs would be required to pay only half of the fees specified in the Schedule under New Drugs and Clinical Trials Rules.

DTAB Subcommittee re-evaluation of FDCs

DTAB Subcommittee called for detailed data to be submitted by 30th June, 2019 for FDCs considered irrational by Kokate Committee and which were being re-evaluated by the Subcommittee. We made a submission to DCG(I) to extend time by three months as the data to be provided was very exhaustive DTAB at their 82nd meeting held on 2nd April 2019 made certain important recommendations on FDCs. Prof.Kokate Committee had reported another batch of 324 FDCs as irrational in second round of assessment. The Committee received 418 applications and found 28 FDCs as rational, 2 FDCs which required further generation of data and 4 FDCs which required further deliberation. 60 of the FDCs in the list of these 418 applications were inadvertently included, as they had already been reviewed by Kokate Committee with 48 FDCs found to be already prohibited, 11 FDCs already declared as rational and 1 FDC was *sub judice*. Therefore, the Committee did not make any recommendations on these 60 FDCs. Following our request and submission to former DCG(I) Dr Eswara Reddy, the date for submission of data for evaluation of FDCs by DTAB was extended from 30th June 2019 to 16th August 2019. The 324 FDCs recommended by Kokate Committee as irrational were listed.

DCG(I) clarification on New Drug Manufacture in own premises

Dr V G Somani, DCG(I) issued a circular dated 30th August 2019 that for approval of manufacturing New Drug, CMC data (Chemistry, Manufacturing and Control) generated in own manufacturing unit could be used to manufacture same product in another own unit with necessary permissions/licenses.

Condition of Undertaking by Marketer of Originality of Brand Name

DTAB, at their 81st meeting on 29th November 2018, had recommended that a mechanism be devised under Drugs and Cosmetic Rules to include provisions for regulating the brand names/ trade names of Pharmaceutical products. Accordingly, the Ministry of Health and Family Welfare published a draft notification (GSR 152 dated 26th February 2019) proposing a condition for grant or renewal of license for all pharmaceutical products The condition required that, for marketing a drug under a brand name / trade name, the applicant would be required to furnish an undertaking to the Licensing Authority that "…such or similar brand name or trade name is not already in existence" so that the brand name or the trade name to be used by the applicant did not lead to any confusion or deception in the market.

We made a submission dated 8 April that the declaration be modified to state that the applicant was the registered owner of the brand name or trade name and such brand name with trade mark was registered with Trademark authority or the application for Trademark registration had been filed and to the best of his knowledge, there was no such or similar brand name or trade name already in existence. In spite of giving such an undertaking, the manufacturers would still need to submit applications for grant of product permission only under a proper name and subsequent to grant of such permission they would be allowed to market their products under the brand name/trade name.

The gazette notification was issued later [vide GSR 828 dated 6th Nov 2019] to provide un undertaking that "to the best of my knowledge based on search in trademarks registry, central data base for brand name or trade name of drugs maintained by CDSCO, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market". A new Form 51 was introduced for the Marketer to sign an undertaking of Ownership of Brand name.

Proposed inclusion of 'Marketer' in D&C Rules

A draft notification [GSR 447 dated 24th June 2019] was issued to define 'Marketer' under Drugs and Cosmetics Rules to make the 'Marketer' also responsible, along with the manufacturer, for ensuring quality and regulatory compliances of the marketed drug. We made a detailed submission on 24th 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. The definition of 'Marketer' as proposed would need to be modified to remove the words 'agent ' or 'person in any other capacity', since these words had wider meaning and were not specific. Also the Marketer could not be considered as an agent of the manufacturer since he worked on a P-to-P contract basis. In our meeting with Dr. Somani, DCG(I) on 15th October 2019, we were informed that the Marketer would be held responsible as proposed only when the Marketer's name was printed on the label along with the manufacturer's and would not be held liable if his name was not included in the label.

New Drugs and Clinical Trials Rules 2019

The New Drugs and Clinical Trials Rules, 2019 was notified vide GSR 227 dated 19th March 2019 for regulation of New Drugs, Investigational New Drugs for human use, Clinical trials, bioequivalence study, bioavailability study and Ethics Committee. Specific Forms were provided in the new Rules for each requirement such as Test License for New Drug, Import, Manufacture, Sale, IND, Clinical Trial, BA/BE study etc to be applied online only through SUGAM portal. All earlier Rules and Forms under Part XA and Schedule Y for New Drug, Test License, Clinical Trials etc were no longer applicable. Fees for all these purposes is increased with even the application for permission to conduct clinical trial itself fixed at Rs 3,00,000 for Phase I, Rs 2,00,000 for Phase II, Rs. 2,00,000 for Phase III and Rs 2,00,000 for Phase IV etc. Also application for permission to conduct BA/BE study is fixed at Rs. 2,00,000. Innovative dosage forms such as sustained release dosage, novel drug delivery etc are now defined as 'New Drug' under the New Drugs and Clinical Trials Rules, 2019. These innovative dosage forms were all these years treated as differentiated dosage forms and novel delivery systems. However the new rules require that clinical Trails, BA/BE studies etc are required to be conducted for approval of even the modified or sustained release forms. This would be a huge cost burden on the manufacturers and could dissuade them from conducting R&D on these drug forms.

Change of API in Formulation while retaining Brand Name

DCG(I) issued a Circular to State Drug Controllers to discourage change of API in formulation while retaining original brand name without change. This matter was discussed in the DCC meetings held in the years 2008, 2010 and 2011. We made a submission on 8th July 2019 agreeing that the use of same brand name by the same manufacturer for a composition meant for entirely different therapeutic segment could pose a risk to the patient and marketing of such products should be discouraged. However, we requested that Brand name be allowed to be retained if change of API was in same therapeutic segment. Also a prefix or suffix in an existing brand name could be allowed with change in API in the same therapeutic segment, as this practice was well accepted by the medical professionals all these years.

CDSCO Workshops for training manufacturers on data requirements

At the meeting of Forum of Associations on 24th June 2019, DCG(I) informed that CDSCO would be organizing Workshops at many pharma-centric cities for providing training to manufacturers on

data requirements for drug product approval on recent amendments to Drugs & Cosmetics Rules. IDMA was entrusted with the task of organising the Workshops at a few venues. We successfully organised Workshops jointly with the Zonal CDSCOs and respective State FDAs at Ahmedabad on 17th August, Chennai on 31st August, and Mumbai & Kolkata on 7th September.

The Workshops covered Requirements of Stability Study and Safety of Excipients, Bioavailability and Bioequivalence Studies, Regulatory Requirements for Grant of Product Approvals, SUGAM and National Drugs Licensing System etc. A combined total of over 1000 delegates participated. Reports, photos and presentations were published in IDMA Bulletin dated 21th September 2019. A list of queries raised at the Workshop at Mumbai was compiled for preparing FAQs by the regulators.

Issues in uploading data on SUGAM portal

Even after the CDSCO Workshops were organized all over the country in August and September and the various issues and concerns in accessing and uploading data on SUGAM portal were discussed, the issues were not yet addressed by CDSCO or CDAC (Centre for Development of Advanced Computing) and not resolved. We made a submission to DCG(I) on 6th November 2019 requesting to direct CDAC to organise Workshops in addressing the issues. As uploading of data on SUGAM portal was already made mandatory, State FDAs and Zonal offices of CDSCO were sending out Notices to companies for not uploading data or for uploading incomplete data. We made a submission dated 19th November requesting DCG(I) to defer implementation of mandatory uploading of data on SUGAM portal by at least a year till the issues were worked out.

Draft D&C Notification proposing QR Code for API packs

A draft notification [GSR 567 dated 8th August 2019) was issued under Drugs and Cosmetics Rules proposing that every API manufactured in India or imported into India would need to carry Quick Response code on its label to facilitate tracking and tracing. Details to be included in the QR Code were also specified. Though the proposal was for confirming the source of the material, printing of the Code was to be implemented at every level of API pack, for both imported and locally manufactured APIs. This raised the issue of maintaining the QR code even when the API was repacked in smaller quantities. Also the container with the QR Code in which the API was imported or supplied could be misused by an unscrupulous dealer to supply any another material. A submission dated 5 September was made to DCG(I) informing of these and other practical issues requesting that the proposal be deferred till the issues were resolved.

DCG(I) updating list of New Drugs

Dr V G Somani, DCG(I) issued a circular dated 18-10-2019 informing that CDSCO was updating the list of New Drugs by collecting information from old registers/files and other sources. To ensure that the list includes all approvals, DCG(I) requested for New Drugs that were not in the available list to be informed to his office along with copy of approval/permission of drugs, including FDCs, new

dosage form, new route of administration etc approved by CDSCO (since 1951), to be submitted by 31th December 2019. We published the circular in the IDMA Bulletin issues dated 30th October and 30 November 2019 along with a Note requesting Members to avail of the opportunity and to ensure that their New Drugs are included in the list by providing the missing details as requested. Members were also informed about the opportunity by email on 26th November 2019.

Authentication of top 300 products/brands

CDSCO proposed voluntary tracking of top 300 products/brands for the domestic market which had high value or high turnover, as 99% of the counterfeits were of these 300 products/brands. Concerned companies were requested to upload information on their websites. DOP had notified that, from April 2020, all medicine packs supplied under Public Procurement Policy would need to carry QR Code containing information on MRP and other details. Bureau of Pharma PSUs of India (BPPI) procured medicines for Jan Aushadhi and had made Data Matrix essential for tertiary level packing. This Data Matrix code contains information about batch number, name, place of manufacture and date of expiry, without price component. DTAB had also recommended QR coding on labels of APIs. Though the pharma packs were labelled with detailed information as required by law, the exercise of tracking and tracing of pharmaceuticals was being taken up by Departments of Commerce, Health and Pharmaceuticals at various levels. Barcoding and serialisation was already being carried out by many companies, especially for exports. However, parent-child relationship and uploading on DAVA portal as desired by Ministry of Commerce for pharma export packs were proving to be impractical.

Meetings with DCG(I) and Jt DCG(I)

We participated in the Forum of Associations meeting on 24th June with former Dr Eswara Reddy, DCG(I). Later we had detailed meetings with Dr Mandeep K Bhandari, Joint Secretary, Health and Mr Arun Singhal, Additional Secretary, Health on 25 June. We also met Dr V G Somani, DCG(I) and Dr Eswara Reddy, Jt DCG(I) on 15th October 2019 at Delhi. We discussed issues as reported above. Details are covered in the General Section.

Awards were distributed during the Annual Day as follows:-

IDMA CORPORATE CITIZEN AWARD 2018	
CATEGORY: TURNOVER ₹500 CRORES AND ABOVE	**BLUE CROSS LABORATORIES PVT LTD**
CATEGORY: TURNOVER LESS THAN ₹500 CRORES	**LINCOLN PHARMACEUTICALS LIMITED**
IDMA MARGI MEMORIAL BEST PATENT AWARDS – 2017-18	
BEST BIOTECH PATENTS AWARD 2017-18	Granted to **M/s BIOCON Ltd.** 25 Patent Families (45 Patents from various Countries)

BEST INTERNATIONAL PATENTS AWARD 2017-18	Granted to **M/s Hetero Drugs Ltd.** 12 APIs, 2 Formulations, 2 Discoveries - includes 8 US, 3 EU, 2 Canada, 3 Indian
BEST INDIAN PATENTS AWARD 2017-18	Granted to **M/s Emcure Pharmaceuticals Ltd.** 12 APIs, 1 NCE
BEST FORMULATION PATENTS AWARD 2017-18	Granted to **M/s Indoco Remedies Ltd.** 3 API (Indian) + 3 Formulations (2 Indian + 1 US)
BEST API PATENTS AWARD 2017-18	Granted to **M/s Aurobindo Pharma Ltd.** 3 APIs (2 Indian + 1 US)
PATENT APPRECIATION AWARD 2017-18	Granted to **M/s Avik Pharmaceutical Ltd.** 1 API (Indian + PCT)
PATENT APPRECIATION AWARD 2017-18	Granted to **M/s Themis Medicare Ltd.** For Formulation Patent (Canada)
PATENT APPRECIATION AWARD 2017-18	Granted to **M/s Gennova Biopharmaceuticals Ltd.** 1 Biotech Patent (Australia)
IDMA QUALITY EXCELLENCE AWARDS - 2018	
Gold Award	**ENCUBE ETHICALS PVT LTD., GOA** *Category: Formulations Unit - Companies with Total Annual Turnover Above ₹100 crores*
Gold Award	**FOURRTS (INDIA) LABORATORIES PVT LTD (PLANT II), CHENNAI** *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*
Silver Award	**GLENMARK PHARMACEUTICALS LTD., INDORE** *Category: Formulations Unit - Companies with Total Annual Turnover Above ₹100 crores*
Silver Award	**APEX LABORATORIES PVT LTD., CHENNAI** *Category: Formulations Unit - Companies with Total Annual Turnover Above ₹100 crores*

IDMA ACG-SCITECH RESEARCH PAPER AWARD – 2018	
REVIEW ARTICLE	Paper: ***Recent Advancements in Graphene Biosensors for the detection of Pathogens - A Review*** Author(s): **Chaudhari A., Jagdale P., Goswami P. and Kerawalla M. A. K.** Institute: Department of Pharmaceutical Science and Technology, Institute of Chemical Technology, Mumbai, Maharashtra, India
PHARMACEUTICAL CHEMISTRY	Paper: ***Structure Elucidation and Biological Investigation of Inorganic Coordination Compounds Derived From Citraconic Anhydride and 5-Amino-1,3,4-Thiadiazole-2-Thiol Organic Moiety*** Author(s): **Gautam S., Singh J., Kumar A., Ravikant and Chandra S.** Institute: Department of Chemistry, Zakir Husain Delhi College, University of Delhi, JLN Marg, New Delhi -110 002, India
NATURAL PRODUCTS	Paper: ***In vitro Hypoglycemic Effects of CaesalpiniaBonducella and MyristicaFragrans Seed Extracts*** Author(s): **Bhutkar M. A., Bhinge S. D., Randive D. S., Wadkar G. H., and Todkar S. S.** Institute: Rajarambapu College of Pharmacy, Kasegaon, Dist – Sangli – Pincode 415 404, Maharashtra, India
PHARMACEUTICS	Paper: ***Box–Behnken Method To Optimize Lornoxicam-Proniosomes: Preparation, In Vitro Characterization And Analgesic Activity*** Authors (s): **Vijaya Sri K., Sandhya D., Manchala M. and Dashamukhi R. S.** Institute: Malla Reddy College of Pharmacy, (Affiliated to Osmania University), MaissammaGuda, Secundrabad - 500 014, Telangana, India
PHARMACEUTICAL ANALYSIS	Paper: ***Simultaneous Determination and Quantitation of Metformin and Teneligliptin in human plasma by LC-ESI-MS/MS with an application to pharmacokinetic studies*** Author(s): **Mandal P., Dan S., Ghosh B., Barma S., Bose R. and Pal T. K.** Institute: Dept. of Pharm. Tech., Jadavpur University, Kolkata - 700 032, India, TAAB Biostudy Services, Kolkata, West Bengal - 700 069, India

PHARMACOLOGY	Paper: ***Bioprospecting of marine halophyte Salicornia europaea L. And evaluation of its biological potential with special reference to anticancer activity*** Author(s): **Samuel P., J. Vijayakumar, Selvarathinam T., R. Deena Dhayalan and K. Amirtharaj** Institute: Department of Biotechnology, AyyaNadar Janaki Ammal College (Autonomous), Sivakasi - 626 123, Tamil Nadu, India

IDMA J B MODY BEST STUDENTS AWARDS-2017

There were 23 Students who received the IDMA JB Mody Best Students Awards from various universities all over India, as follows: They were presented with a Cash Award, a Certificate and a Memento.

1.	**Ms. Y. Achyutha Valli Devi,** B. Pharm 2017, Andhra University, Visakhapatnam
2.	**Mr. Harsh Barua,** B. Pharm 2017, BharatiVidyapeeth's College of Pharmacy, Navi Mumbai
3.	**Mr. Dharmik Joshi,** B. Pharm 2017, Birla Institute of Technology, Mesra, Ranchi (Jharkhand)
4.	**Ms Seema Gupta,** B. Pharm 2017, C. U. Shah College of Pharmacy, Mumbai
5.	**Ms. Krishna Baxi,** B. Pharm 2017, Dr.Bhanuben Nanavati College of Pharmacy, Mumbai
6.	**Ms. Payal Parmar,** B. Pharm 2017, Gujarat Technological University
7.	**Ms. Swapna Kumari,** B. Pharm 2017, Guru Ghasidas Vishwavidyalaya, Bilaspur, Chattisgarh
8.	**Ms. Suchitra Sankaranarayan,** B. Pharm 2017, Institute of Chemical Technology, Mumbai
9.	**Ms. Srushti Sodha, B.Tech. (Pharma) 2017,** Institute of Chemical Technology, Mumbai
10.	**Ms. Rumaisa Jan,** B. Pharm 2017, Kashmir University, J & K, Srinagar
11.	**Ms. Vrishali Salian,** B. Pharm 2017, Principal K.M. Kundnani College of Pharmacy, Mumbai
12.	**Ms. Sampada Sewalkar,** B. Pharm 2017, Rashtrasant Tukadoji Maharaj Nagpur University
13.	**Dharmanath Parbat,** B. Pharm 2017, RGUHS University, Bangalore
14.	**Ms. Puravi Nayak,** B. Pharm 2017, Siksha 'O' Anusandhan University, Bhubaneswar
15.	**Ms. Salavi Vedanti,** B. Pharm 2017, Shivaji University, Kolhapur
16.	**Drashti Upadhayay,** B. Pharm 2017, The Maharaja Sayajirao University of Baroda

17.	**Ms GiteSuvarna,** B. Pharm 2017, SNDT Women's University, Mumbai
18.	**Mr. Dharmesh Mehta,** B. Pharm 2017, VES College of Pharmacy, Mumbai
19.	**Ms. Uma Maheshwari R,** B. Pharm 2017, Annamalai University, Annamalainagar, T.N.
20.	**Ms. Amanpreet Kaur,** B. Pharm 2017, Baba Farid University of Health Sciences Faridkot (Pb.)
21.	**Mr. Abhishek Kulkarni,** B. Pharm 2017, Bombay College of Pharmacy, Mumbai
22.	**Ms. Gunja Chandani,** B. Pharm 2017, Dr.Harisingh Gour Vishwavidyalaya, Sagar, M.P.
23.	**Ms. Anjali,** B. Pharm 2017, Panjab University, Chandigarh

IDMA REPRESENTATIONS IN THE YEAR 2019

	Subject	Date of Submission	Representation to
1.	Comments and Suggestions on Draft Patents (Amendment) Rules, 2018	31.12.2018	Shri Rajiv Aggarwal, IAS, Joint Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, New Delhi Shri Sushil K Satpute, Director, Department of Industrial Policy & Promotion, Ministry of Commerce, New Delhi
2.	IDMA meeting with Shri Anil Diggikar, Principal Secretary Environment, and further action	02.01.2019	Shri Bhushan Gagrani Principal Secretary Office of Chief Minister Government of Maharashtra
3.	Proposal to allow Drug Substitution for Jan Aushadhi Stores – 81st meeting of the DTAB regarding held on 29th November 2018	02.01.2019	Dr. S. Eswara Reddy Drugs Controller General (I) Central Drugs Standard Control Organisation
4.	Disposal of Public Grievances through PG Portal IDMA letter dated 27.11.2018 addressed to Hon'ble Dr. Harsh Vardhanji, Minister of Environment, Forest & Climate Change and Earth Sciences	03.01.2019	Shri Gurnam Singh Additional Director& I/C, IPC-1 Central Pollution Control Board

5.	Request for removal of brackets G.S.R. 222 (E) dated 13th March 2018	16.01.2019	Dr. Mandeep K Bhandari, IAS, Joint Secretary (Regulations), Dept. of Health & Family Welfare
6.	Request for clarification in relation to ascertaining 'quantity' of pharmaceutical preparations covered under the Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS Act)	17.01.2019	The Under Secretary (Drugs) Ministry of Health and Family Welfare
7.	Representation in response to draft rules published under GSR 999 (E) dated 5.10.2018 to substitute existing Schedule M of the Drugs and Cosmetics Rules, 1945.	17.01.2019 /18.01.2019	1. Dr. Vinod K Paul, Member, NITI Aayog 2. Mr. Jai Priye Prakash, Secretary, Dept. of Pharma 3. Mr. Shyamal Misra, Joint Secretary (Commerce) 4. Dr. K.V. Nagi Reddy, Director (Commerce) 5. Mr. Sushil K Satpute, Director, DIPP & 6. Mr. V. Seshadri, Joint Secretary to the Prime Minister of India.
8.	Drugs (Prices Control) Amendment Order 2019 Ref: S.O. 39 (E) dated 3rd January 2019	29.01.2019	1. Shri Jai Priye Prakash, Secretary, Dept. of Pharma 2. Shri Navdeep Rinwa, IAS, Jt. Secretary, Dept. of Pharma
9.	Issuance of final notification to include Organ Preservative Solution as Medical Device under Drugs & Cosmetics Act, 1940	31.01.2019	Ms. Preeti Sudan, IAS, Secretary to the Govt. of India Ministry of Health & Family Welfare Cc: Dr. S. Eswara Reddy, DCGI CC: Dr. Mandeep K. Bhandari, IAS, Jt. Secretary to the Govt. of India, Ministry of Health & Family Welfare
10.	Letter to CPCB requesting for clarification on need for seeking prior permission from CPCB or SPCBs	13.02.2019	Shri Gurnam Singh Addl. Director /Scientist E Central Pollution Control Board
11.	Unfair Tender condition/Fall clause of seeking "Lowest Rates than quoted to any other Institution"	13.02.2019	Shri. Jai Priye Prakash, Secretary, Dept. of Pharma

12.	Issues with Ministry of Environment on APIs	14.02.2019	Dr. K.V. Nagi Reddy, Director Department of Commerce, Ministry of Commerce & Industry
13.	Regulation of Controlled Substances RCS Order, 2013 – proposal to bring preparations of Ephedrine and Pseudoephedrine under Schedule A	19.02.2019	Dr. Naresh Sharma, Deputy Drugs Controller
14.	Trade Margins	21.02.2019	Hon'ble Dr. Vinod K. Paul Member, Niti Aayog
15.	Meeting with major Pharma companies to discuss Pharma Sector Issues	26.02.2019	Hon'ble Shri Suresh Prabhu ji Minister of Commerce & Industry
16.	Substances recommended to be added to Schedule I of the 1961 and Schedule II of the 1971 convention.	07.03.2019	Ms. Remya Prabha G Deputy Director Dept. of Pharmaceuticals
17.	Negotiations on proposed Preferential Trade Agreement between India and Iran	01.04.2019	Mr. R.K. Aggarwal, Under Secretary, DoP
18.	Hardship faced by Exporters in Post Audit of Refunds	01.04.2019	Shri Pranab Kumar Das, Chairman Central Board of Indirect Taxes & Customs (CBIC)
19.	Proposal to introduce Undertaking of originality of brand name by applicant marketer under D&C Rules Ref: Draft Notification GSR (E) 152 dated 26 February 2019	08.04.2019	The Under Secretary (Drugs) Ministry of Health and Family Welfare Government of India Cc: Dr. S. Eswara Reddy, DCGI
20.	First meeting of the Expert committee to discuss the issues being faced by Pharma exporters on the implementation of the bar coding and Track & Trace system for export of Pharmaceutical products and uploading of data on DAVA Portal	10.04.2019	Shri Shyamal Misra, Joint Secretary (Commerce)

21.	Our letter dtd. February 15, 2019 requesting for a follow up on the joint meeting of IDMA and MPCB on 26th December 2018	16.04.2019	Shri Anil Diggikar, IAS Principal Secretary, Environment Government of Maharashtra Mumbai
22.	DoP letter dated 13.03.2019 on Special One Time Settlement (SOTS) Scheme for overcharging cases under DPCO, 1979/87/1995 – reg	22.04.2019	Mr. Jai Priye Prakash, Secretary, Dept. of Pharma
23.	Comments for the 17th Expert Committee meeting to finalize the Environmental Standards	24.04.2019	Ms. Remya Prabha Deputy Director Dept. of Pharmaceuticals
24.	Inviting public comments on Draft (revised) Guidelines on Access to Biological Resources and Associated Knowledge and Equitable Sharing of Benefits Regulations, 2019	01.05.2019	Dr. B. Meenakumari, Chairperson, National Biodiversity Authority,
25.	Ease of business for Gujarat based Chemical Industry	06.05.2019	Member Secretary Gujarat Pollution Control Board
26.	Periodic interaction and joint training programmes to create awareness – reg	30.05.2019	The Director General Directorate of Revenue Intelligence
27.	Meeting Notice dated 29th May, 2019 to discuss the issues pertaining to DAVA Portal based on the experience of CDSCO for Track & Trace System for export of Pharmaceutical products.	30.05.2019	Shri Shyamal Misra IAS Joint Secretary to the Government of India, Department of Commerce, Ministry of Commerce and Industry
28.	Brief note of Pre-Budget 2019-20 – meeting held on 24.05.2019	31.05.2019	Mr. P K Das, Chairman, CBIC Mr K C Varshney, Joint Secretary, (TPL-1), CBIC Mr G D Lohani, Joint Secretary (TRU), Mr Javed Akthar, Director (TPL) Mr Mahipal Singh, IRS, Budget Officer.

29.	USTR 2019 Special 301 Report & "Bottle of Lies" by Katherine Eban	04.06.2019	Shri Shyamal Misra, IAS Joint Secretary to the Government of India, Department of Commerce CC: The Secretary to the Government of India, Department of Pharmaceuticals, CC: The Drugs Controller General (India), Central Drugs Standard Control Organisations
30.	IDMA's Submission on Draft Patents (Amendment) Rules, 2019	12.06.2019	Mr. Sushil K Satpute, Director, DPIIT
31.	Authentication of Exports of Indian Pharma Products	13.06.2019	Shri N.K. Joshi Under Secretary to the Govt. of India Dept. of Pharmaceuticals Ministry of Chemicals & Fertilizers
32.	Income Tax Benefit for R&D Expenses for Pharmaceutical Industry	27.06.2019	Shri K.R. Vaidheeswaran, IAS Joint Secretary to the Government of India Department of Scientific and Industry Research
33.	Representation on data of 83 FDCs- 4 month extension	8th July 2019	Dr. S. Eswara Reddy, Drugs Controller General India Central Drugs Control Standard Organization FDA Bhawan, New Delhi
34.	Changing API in drug formulation but retaining the Brand name	8th July 2019	Dr. S. Eswara Reddy, Drugs Controller General India Central Drugs Control Standard Organization FDA Bhawan, New Delhi
35.	Need for Relaxation in Current Procedures to Boost API Manufacture	8th July 2019	Dr. S. Eswara Reddy, Drugs Controller General India Central Drugs Control Standard Organization FDA Bhawan, New Delhi

36.	Suggestions on Review of the Foreign Trade Policy	15th July 2019	Shri Pradyumma Sahu Foreign Trade Development Officer Directorate General of Foreign Trade Department of Commerce Udyog Bhawan New Delhi
37.	Note to Shri Navdeep Rinwa for CLCSS and PTUAS	15th July 2019	Shri Navdeep Rinwa, IAS Joint Secretary (Policy) Department of Pharmaceuticals Shahstri Bhawan New Delhi
38.	Revival on API Industry in Maharashtra – MPCB issues	19th July 2019	Dr. Pallavi Darade FDA Commissioner Mumbai
39.	Proposal to define/include ''Marketer'' under Drugs & Cosmetics Rules	24th July 2019	The Under Secretary (Drugs) Ministry of Health and Family Welfare Government of India Nirman Bhavan New Delhi
40.	Revision of NLEM – ICMR	25th July 2019	Prof. Balram Bhargava Secretary Indian Council of Medical Research (ICMR) New Delhi
41.	Comments/Inputs for India-Israel FTA	26.07.2019	Mr. N K Joshi Under Secretary, DoP
42.	Request to Health Ministry-Govt Institutions mandating USFDA's approval	6th August 2019	The Joint Secretary, Health CC: 1. The Secretary, DOP 2. OSD, DPI IT
43.	Licensing Requirement Adherence Deadline for Implementing	14th August 2019	Shri Shobit Jain Executive Director (Compliance Strategy) Food Safety & Standards Authority of India FDA Bhawan, New Delhi CC: 1. Ms. Rita Teotia, Chairperson, FSSAI 2. Shri Pawan Kumar Agarwal, CEO, FSSAI

44.	Negative Government Pollution Control Monitoring Policy Hindering Growth of Chemical and Pharmaceutical Industry	28th August 2019	Shri Prakash Javadekar Hon'ble Minister for Environment, Forests and Climate Change Government of India, New Delhi
45.	Anomalies in Pharma products listing for Merchandise Exports from India Scheme (MEIS) benefit	03.09.2019	Dr. Alok Vardhan Chaturvedi, DGFT, New Delhi
46.	Proposed Rule to introduce QR Code for all levels of manufactured or imported API packs	5th September 2019	The Under Secretary (Drugs) Ministry of Health and Family Welfare Government of India Nirman Bhavan, New Delhi
47.	Request of withdrawal of Lesser Duty Rule – Anti-dumping duty and Countervailing duty rules	9th September 2019	Shri Piyush Goyal Hon'ble Commerce & Industry Minister Udyog Bhawan, New Delhi
48.	Letter to Chairman CPCB on environmental issues	13th September 2019	Shri S. P. Singh Parihar, IAS, Chairman Central Pollution Control Board Parivesh Bhawan, Delhi
49.	Reply to MPCB regarding environmental issues	16th September 2019	Mr. E. Ravendiran, IAS Member Secretary Maharashtra Pollution Control Board Mumbai CC: 1. Shri Anil Diggikar, IAS Principal Secretary, Environment, Govt. Of Maharashtra 2. Hon'ble Chairman – MPC Board, Sion, Mumbai
50.	Request for extension of effective date of implementation of Addendum 2019 to Indian Pharmacopoeia 2018	18th September 2019	The Secretary-Cum-Scientific Director Indian Pharmacopoeia Commission Ministry of Health & Family Welfare Government of India, Ghaziabad
51.	IDMA- BDMA(I) Joint representation to CPCB	20th September 2019	Shri S. P. Singh Parihar, IAS Chairman, Central Pollution Control Board, Parivesh Bhawan, Delhi

52.	Interaction Meeting on 10.10.2019 at CPCB with Pharma Associations, MoEF&CC, CPCB, SPCBs, Department of Pharmaceuticals	30th September 2019	Shri S. P. Singh Parihar, IAS Chairman, Central Pollution Control Board, Parivesh Bhawan, Delhi
53.	Letter to MPCB	30th September 2019	Mr. E. Ravendiran, IAS Member Secretary Maharashtra Pollution Control Board Kalpataru Point, Mumbai
54.	Valuation of Goods transferred to branches/ depots – Request for clarification – reg	3rd October 2019	The Chairman, Central Board of Indirect Taxes and Customs, Ministry of Finance New Delhi
55.	CPCB/SPCBs/Industry interactive workshop	10th October 2019	Shri S. P. Singh Parihar, IAS Chairman Central Pollution Control Board Parivesh Bhawan, Delhi
56.	IDMA/BDMA's comments on presentation made by CPCB on 10th Oct 2019	29th October 2019	Shri S. P. Singh Chairman Central Pollution Control Board Parivesh Bhawan, Delhi CC: Shri Hardik Satishchandra Shah, IAS Deputy Secretary to the Govt. of India Prime Minister's Office New Delhi
57.	List of APIs and Intermediates 1. List of APIs not manufactured in India 2. List of APIs recommended for increase in Import Duty 3. List of Intermediates recommended for reduction in Import Duty	5th November 2019	Ms. Sumita Dawra, IAS Jt Secretary to the Government of India Dept of Promotion of Industry and internal Trade Udyog Bhawan, New Delhi
58.	IPDMS issues	6th November 2019	Ms. Remya Prabha G. Deputy Director Dept of Pharmaceuticals Shastri Bhawan New Delhi

59.	SUGAM Portal Workshops with CDAC	6th November 2019	Dr. V G Somani Drugs Controller General (I) Central Drugs Standard Control Organisation FDA Bhawan, New Delhi
60.	FDC fee at Rs. 15000	6th November 2019	Dr. V G Somani Drugs Controller General of India Central Drugs Standard Control Organisation FDA Bhawan, New Delhi
61.	Amendments to RCS Order 2013	28th November 2019	Shri Ritwik Ranjanam Pandey, IAS Joint Secretary to the Government of India Department of Revenue Ministry of Finance, New Delhi
62.	Applicability of sub-clause(i) to clause (a) of Rule 67-A in Chapter VII-A of NDPS Rules, 1985 to Research Institution registered with DSIR	28th November 2019	Mr. Dinesh Bouddh, Director (Narcotics) Room No 48-C, North Block Department of Finance Government of India, New Delhi
63.	Seeking to retain exemption from 'Fall Clause' provided to Drugs	27th November 2019	The Secretary, Department of Expenditure, Ministry of Finance New Delhi Cc: The Secretary, DoP
64.	Pre-Budget Proposals 2020-21 on Direct Taxes and Indirect Taxes	13 December 2019	Dr John Joseph, Member, CBIC

MEETINGS IN THE YEAR 2019

Date	Meetings
03.01.2019	Press meeting for India Pharma & Medical Device 2019, Delhi
11.01.2019	Meeting regarding Quality Excellence Award, IDMA office
15.01.2019	Meeting to discuss the draft of "New Industrial Policy" related to Pharma sector, Mumbai
17.01.2019	Meeting with Central Pollution Control Board, CPCB office, New Delhi
19.01.2019	IDMA Annual General meeting, Mumbai
01.02.2019	Pharmexcil COA meeting, IDMA office
06.02.2019	Meeting with Dr. Deenbandhu Gowda, CPCB, New Delhi
06.02.2019	3rd meeting of Task Force on Active Pharmaceutical Ingredients - regarding, New Delhi

09.02.2019	Meeting of Advisory Board of Pharma & Healthcare Management, IES, Mumbai
26.02.2019	Meeting regarding Narcotics at Narcotics Control Bureau, New Delhi
26.02.2019	Express Pharma CEO Roundtable, Mumbai
27.02.2019	Meeting with Additional Development Commissioner and Joint Secretary MSME, Delhi
27.02.2019	IDMA National Executive Committee Meeting at Mumbai
28.02.2019	Meetings at Delhi with 1. Mr Sudhansh Pant, Joint Secretary (Health) 2. Mr Arun Singhal, Addl Secretary (Health) 3. Dr Mandeep Bhandari, Joint Secretary (Health) 4. Mr Navdeep Rinwa, Joint Secretary, DoP
05.03.2019	Meeting with stakeholders for holding comprehensive discussions in order to address the issues pertaining to the implementation of Track and Trace system for export of Pharma product and maintaining, New Delhi
22.03.2019	Executive Committee Meeting, Mumbai
25.03.2019	Fifth meeting of Indian Drug/Pharmaceuticals Association Forum regarding, New Delhi
22.04.2019	2nd meeting of Joint Administration Committee (JAC) under expanded India
24.04.2019	Consultative Meeting on Pharmaceutical Items in WPI, New Delhi
26.04.2019	IDMA National Executive Committee Meeting at Mumbai
17.05.2019	Interactive Meet on New Drugs & Clinical Trials Rules 2019, it's understanding and impact – THSTI
23.05.2019	IDMA National Executive Committee Meeting at Mumbai
24.05.2019	Pre-Budget meeting for Union Budget 2019-2020, Delhi
31.05.2019	First meeting of the Expert Committee to discuss the issue being faced by Pharma exporters on implementation of the barcoding and Track & Trace
10.06.2019	Issues related to regulation of sales of drugs over internet Delhi (GSR 817(E), dt.28.8.2019)
13.06.2019	Meeting of Expert Committee to discuss suggestion received form implementation of simple system for authentication of pharmaceutical exports New Delhi
19.06.2019	Stakeholders Consultation meeting on Patents (Amendment) Rules, 2019 New Delhi
21.06.2019	IDMA National Executive Committee Meeting, and Interactive Session with IDMA-GSB at Ahmedabad
24.06.2019	Meeting with Dr. Vinod K Paul, Member, NITI Aayog, Delhi
24.06.2019	6th Indian Drug/Pharma Association Forum meeting, Delhi

25.06.2019	Meeting with Mr. Arun Singhal, Addl. Sec. (Health) Meeting with Dr. Mandeep Bhandari JS Health Meeting with Mr. Navdeep Rinwa, JS, DoP Meeting with Mrs. Shubhra Singh, Chairperson, NPPA
27.06.2019	Meeting to discuss measures to be ten for enhancing pharma exports and reducing import dependency on APIs. KSMs – Chair – Hon'ble Mr. Som Parkash, MoS, Commerce & Industry, New Delhi
18.07.2019	Jaykumar Rawal, Minister for Tourism & Employment Guarantee Scheme, Govt of Maharashtra Reg- API Manufacturers in Mahrashtra- specially on environment related issues, at Collector's Office, Thane
22.07.2019	Canadian Networking Reception, Mumbai
23.07.2019	RCEP stakeholder meeting on chemicals, pharma, plastics, rubber, leather, textiles New Delhi
25.07.2019	First stakeholders National Consultation meeting of SNCM for revision of NLEM 2015 New Delhi
26.07.2019	IDMA National Executive Committee Meeting at Mumbai
06.08.2019	7th Edition of India Pharma Awards (Pre Jury Advisory meet) Mumbai
17.08.2019	IDMA National Executive Committee Meeting, and Interactive Session with IDMA TNPKSB at Chennai
20.08.2019	Meeting with Smt. Ritu Dhillon, Member Secretary, NPPA Meeting with Mrs. Shubhra Singh, Chairperson NPPA Meeting with Dr. P.D. Vaghela, Secretary, DoP Meeting with Mr. Navdeep Rinwa, Joint Secretary, DoP
23.08.2019	First meeting of DoP Forum of Pharma Associations New Delhi
06.09.2019	Meeting on Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) New Delhi, Chair – Member Secretary, NPPA & Joint Secretary (Policy), DoP
16.09.2019	Meeting with Shri E. Ravendiran, IAS Member Secretary, MPCB regarding supporting Bulk Drug industry in Maharashtra by facilitating the ease of doing business, Mumbai
19.09.2019	Stakeholders consultation on Chemicals and Pharma for RCEP negotiations, New Delhi – Chair: Hon'ble Minister Shri Piyush Goyal
26.09.2019	10th SOH Awards, Mumbai
27.09.2019	IDMA National Executive Committee Meeting at Mumbai
01.10.2019	Meeting of Expert Committee to discuss existing standards for major chemicals and recommending for their BIS mandatory, New Delhi Chair – Joint Secretary (Chemicals)

04.10.2019	IDMA Conference on Creating Value Through Partnerships 2019, Mumbai
7.10.2019	E. Ravendiran, Member Secretary, MPCB, Mumbai
10.10.2019	Interaction meeting of Chairman, CPCB with Pharma Associations, MoEF, SPCBs and Ministries @ Parivesh Bhawan, 2nd floor Conference Room), CPCB Delhi
15.10.2019	Dr. S Eswara Reddy, Joint Drugs Controller, Delhi Dr. V.G. Somani, DCG(I), Delhi. Dr. P.D. Vaghela, IAS, Secretary to the Govt. of India, Dept. of Pharmaceuticals, Delhi Mr. Navdeep Rinwa, IAS, Joint Secretary to the Govt. of India, Dept. of Pharmaceuticals, Delhi Mr. Rajneesh Tingal, Joint Secretary to the Govt. of India, Dept. of Pharmaceuticals, Delhi.
16.10.2019	Mr. Arun Singhal, IAS, Addl. Secy to the Govt. of India, Ministry of Health & Family Welfare, New Delhi. Dr. Mandeep K Bhandari, IAS, Joint Secy to the Govt. of India, Ministry of Health & Family Welfare, New Delhi. Mrs. Shubhra Singh, IAS, Chairperson, NPPA, New Delhi.
17.10.2019	Discussion on Next Steps RDD Asia 2020
17.10.2019	Meeting with Prachi Singhai, IDMA Office, Mumbai
18.10.2019	Inauguration Ceremony of new office of PHARMEXCIL at Andheri, Mumbai
18.10.2019	IDMA National Executive Committee Meeting at Mumbai
01.11.2019	CETP meeting at Mantralaya at 11.00 a.m.
04.11.2019	Joint Steering Committee meeting on India Pharma 2020 & India Medical Device 2020" New Delhi
04.11.2019	Consultation for revision of NLEM, New Delhi
11.11.2019	Meeting for Finalising list of co-opted members & special invitees for Executive Committee 2020-2021, Mumbai
11.11.2019	Stakeholder consultation workshop for Carbon Market opportunities for MSMEs to improve energy efficiency and strengthen engagement for Climate Action, Delhi
15.11.2019	USP's Inaugural South Asia stakeholder meeting, New Delhi
16.11.2019	IDMA National Executive Committee Meeting and Interactive Session with IDMA WBSB Members at Kolkata
27.11.2019	Meeting with Associations of stakeholders industry for putting certain chemicals (Phenol/Acetone; Caustic soda, Fatty alcohols/Acids) in the Restricted List at Shastri Bhawan, Delhi
28.11.2019	Meeting with Mr. Sachin Balpande, Trade Commissioner at Consulate General of Canada, IDMA Office, Mumbai

11.12.2019	Meeting to discuss recommendations for faster growth in Pharma / Medical Device sector, Delhi Chair – Secretary, DoP
11.12.2019	Concall with Ms. Jessica Sin, International Sales Director and Mr. Xinwei Zhao , Project Manager, Reed Sinopharm Exhibitions & the 84th API China.
11.12.2019	Meeting with Mr. Takashi Fuzukawa, Managing Director and Mr R Jayakumar, Manager Sales & Marketing, Toyobo India Pvt Ltd. Mumbai
13.12.2019	Pre-Budget meeting for Union Budget 2020-21 at New Delhi
20.12.2019	IDMA National Executive Committee Meeting at Mumbai
23.12.2019	Meeting to review the implementation of UCPMP New Delhi. Chair – Secretary, DoP

SEMINARS AND CONFERENCES IN THE YEAR 2019

Date	Meetings
19.01.2019	IDMA Annual Day Celebrations, Mumbai
14.02.2019	100 Most Impactful Healthcare Leaders – Global Listing at World Health & Wellness Congress, Taj Lands' End, Mumbai
18 & 19.02.2019	India Pharma 2019, Hotel Lalit Ashok, Bangalore
21 to 23.02.2019	PPL Conclave 2019 organised by Express Pharma, Hyderabad
22.03.2019	56th Indian Drugs Annual Day, IES, Mumbai
15.04.2019 to 18.04.2019	South Asian College an affiliate of American College of Clinical Pharmacology Conference, Mumbai
10.05.2019	IDMA Marketing and Sales Conference – 'Growing Brands to Level Next', Mumbai
21.05.2019	8th edition of InnoPack Pharma Confex, Mumbai
24 and 25.05.2019	21st IDMA APA Pharmaceutical Analysts' Convention
28 and 29.06.2019	Pharmac South 2019, IDMA-TN PKSB at Chennai
06.08.2019	7th Edition of India Pharma Awards (Pre Jury Advisory meet) Mumbai
10.08.2019	CDSCO (EZ)–Pharmexcil-IDMA WBSB Workshop-cum-Seminar on 'Recent Advancements in Indian Drug Regulations with reference to Draft Schedule-M'
17.08.2019	CDSCO – FDA- IDMA Workshop for providing training to manufacturers on the data requirements for drug product approval under the recent amendments to the Drugs and Cosmetics Rules, 1945 at Ahmedabad
31.08.2019	CDSCO – FDA- IDMA Workshop for providing training to manufacturers on the data requirements for drug product approval at Chennai

07.09.2019	CDSCO – FDA- IDMA Workshop for providing training to manufacturers on the data requirements for drug product approval at Mumbai
07.09.2019	CDSCO – FDA- IDMA Workshop for providing training to manufacturers on the data requirements for drug product approval at Kolkata
19.09.2019	7th Pharma Pro & Pack Expo 2019 and India Lab Expo 2019, Hyderabad
21.09.2019	IDMA Marketing and Sales Conference – 'Growing Brands to Level Next', Kolkata
23.09.2019	BMJ Convergence 2019, Chief Guest Mr Daara Patel, Secretary-General, Mumbai
26.09.2019	10th SOH Awards, Mumbai
04.10.2019	IDMA Conference on 'Creating Value Through Partnerships 2019', Mumbai
17.10.2019	Discussion on Next Steps RDD Asia 2020
18.10.2019	Inauguration Ceremony of new office of PHARMEXCIL at Andheri, Mumbai
7 to 9.11.2019	Pharmac India 2019, IDMA-GSB, Ahmedabad
20.11.2019	KPMG Interactive Session on Corporate Tax Ordinance 2019, IDMA Office, Mumbai.
20.11.2019	5th ABP News Healthcare Leadership Awards, Mumbai
25.11.2019	Pharma Ratna Award 2019 & International Pharmaceutical Conference, organised by 'Rab Di Meher', New Delhi
09.12.2019	Insight 2019 (Annual Pharma Conference of Indian Education Society Management College & Research Centre IES MCRC), Mumbai
18.12.2019	16th Edition of Frost & Sullivan India Manufacturing Excellence Awards (IMEA) 2019, Mumbai
20 to 22.12.2019	71st Indian Pharmaceutical Congress, 2019 hosted by AIDCOC and supported by IDMA

IDMA REPRESENTATION IN COMMITTEES

- Technical Committee on Pharmaceuticals Technological Upgradation Assistance Scheme (PTUAS) – constituted by Department of Pharmaceuticals
- Department of Pharmaceuticals Forum of Associations
- 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 for 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 – 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)
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- 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
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- Constitution of Sub-committee on FDCs headed by NilimaKshirsagar, ICMR, Mumbai – vide 81st meeting of DTAB, dt.29.11.2018
- Sub-committee on FDC – Flupenthixol + Melitracen for Human Use – headed by Dr.NilimaKshirsagar, 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.NilimaKshirsagar, ICMR, Mumbai. – vide 81st meeting of DTAB, dt.29.11.2018

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