INDIAN DRUG MANUFACTURERS' ASSOCIATION

Since 1961

# Innovating Today

## For Healthier Tomorrow

ANNUAL REPORT 64th 2025

**Delivering Healthcare to the World!!**

# N O T I C E

The 64th Annual General Meeting of the Indian Drug Manufacturers' Association (IDMA) will be held on **Friday, 13th February 2026 at Strategy Hall, Hotel Taj Santacruz, Mumbai at 4:00 PM** to transact the following business:

## AGENDA

1. To read the Notice convening the meeting.
2. To adopt the Annual Report for the year 2025.
3. To adopt the Audited Statement of Accounts for the year ended 31st March 2025.
4. To appoint Auditors for the year 2026-2027.
5. To Announce the Executive Committee Meetings Schedule for 2026.
6. Any other business with the permission of the Chair.

**Looking forward to welcoming you at the 64th Annual General Meeting at 4:00 PM.**

Daara B Patel
Secretary - General

Date: 29th January 2026

*Note : Members who need clarifications or details with regards to the Agenda for the meeting are required to write to IDMA Head office specifying the clarification required by them on or before 6th February 2026.*

# IDMA EXECUTIVE COMMITTEE 2025

**NATIONAL PRESIDENT**

**Mr. Bharat N Shah**
Managing Director
**S. Kant Healthcare Ltd.**
A-3, Shiv Sagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018

**IMMEDIATE PAST NATIONAL PRESIDENT**

**Dr. Viranchi Shah**
Director
**Saga Lifesciences Limited**
404-405, South Tower, One 42 Building, Iscon Ambli Road, Ambli, Ahmedabad

**SR. VICE PRESIDENT**

**Dr. George Patani**
Director
**Inga Laboratories P. Ltd.**
Inga House, Mahakali Road, Andheri East, Mumbai - 400 093

**VICE-PRESIDENTS**

***Western Region***

**Mr. Mehul M. Shah**
Promoter & Managing Director
**Encube Ethicals Pvt. Ltd.**
803, B Wing, HDIL Kaledonia, Sahar Road, Andheri (E), Mumbai - 400 069

***Northern Region***

**Mr. Bal Kishan Gupta**
Chairman
**Medicamen Organics Limited**
10, Community Centre No.2, Ashok Vihar Phase-II, Delhi-110 052

***Southern Region***

**Mr. T. Ravichandran**
Managing Director
**Pharm Products Pvt. Ltd.**
No. 40, A – Block, 6th Street,
Anna Nagar East, Chennai – 600 102

| | |
|---|---|
| ***Eastern Region*** | **Mr. Asheesh Roy**<br>Director<br>**Stadmed Pvt. Ltd.**<br>Kumud, 14 A, Monoharpukur Road,<br>Kolkata - 700 026 |
| **HON. GENERAL SECRETARY** | **Ms. Aditi Kare Panandikar**<br>Managing Director<br>**Indoco Remedies Limited**<br>Indoco House, 166 CST Road, Kalina,<br>Santacruz (East), Mumbai - 400 098 |
| **HON. JOINT SECRETARY** | **Mr. Kamlesh C. Patel**<br>Managing Director<br>**West-Coast Pharmaceutical Works Ltd.**<br>Meldi Estate, Nr. Prasang Party Plot,<br>Opp. Sola Bhagwat, Sayona City Road,<br>Gota, Ahmedabad – 382 481, Gujarat |
| **HON. JOINT SECRETARY** | **Dr. Shrenik Kantilal Shah**<br>Director<br>**Montage Laboratories Pvt. Ltd.**<br>At. Dhandha, Idar Road,<br>Himatnagar – 383 001, Gujarat, India |
| **HON. TREASURER** | **Mr. B. G. Barve**<br>Joint Managing Director<br>**Blue Cross Laboratories Pvt. Ltd.**<br>Peninsula Chambers, Peninsula Corporate<br>Park, G.K. Marg, Lower Parel (W),<br>Mumbai - 400 013 |

**ELECTED MEMBERS**

| | |
|---|---|
| **Mr. Ashok Kundanmal Dhoka**<br>*Director*<br>**Maxim Pharmaceuticals Pvt. Ltd.**<br>08, Kshitij Chs,Suryakant Kahtu Marg,<br>Salisbury Park, Gultekdi,<br>Pune - 411 037 | **Mr. Bhavin Mukund Mehta**<br>Director<br>**Kilitch Drugs India Ltd.**<br>37, Ujagar Industrial Estate, W.T.Patil Marg,<br>Deonar, Mumbai-400 088, Maharashtra |

**Mr. Devesh Malladi**
*Managing Director*
**Embio Limited**
501, 5th Floor, Central Avenue Road,
Hiranandani
Gardens, Powai - 400 076

**Mr. Harpal Vala**
*Managing Director*
**Kepler Healthcare Pvt. Ltd.**
9, Solitaire Sky, Beside Hyatt Regency,
Ashram Road, Ahmedabad - 380 014,
Gujarat

**Ms. Neha Thakore**
*Director*
**Avik Pharmaceutical Ltd.**
194 Arvind Chamber, Sai Service Compound,
Western Express Highway, Andheri East,
Mumbai - 400 069

**Mr. Probhas Bondhu Chakraborty**
*Managing Director*
**Mendine Pharmaceuticals Pvt. Ltd.**
36 A & B Alipore Road,
Kolkata - 700 027

**Mr. Sachin Navinchandra Doshi**
Whole Time Director
**DWD Pharmaceuticals Ltd.**
404/4th Floor, Dalamal House,
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Mumbai - 400 021

**Mr. Tushar Anil Korday**
Director
**Emil Pharmaceutical Industries Private Limited**
301, The Western Edge-1, Condominium,
Above Metro Mall W.E. Highway, Magathane,
Borivali (East), Mumbai - 400 066

**Dr. Chinmay Majmudar**
*Director*
**Bakul Aromatics and Chemicals Pvt. Ltd.**
Sterling Centre, Dr. Annie Besant Road, Worli,
Mumbai - 400 018

**Mr. Nandan Chandavarkar**
Jt. Managing Director
**FDC Limited**
FDC House, C-11 & 12, Dalia Industrial
Estate, Oshiwara Village, Off New Link Road,
Andheri - West, Mumbai – 400053.
Maharashtra, India

**Mr. Nirav K. Mehta**
*Managing Director and CEO*
**Corona Remedies Limited**
"CORONA House", C – Block, Mondeal
Business Park, Near Gurudwara, S. G. High-
way, Thaltej, Ahmedabad – 380 059, Gujarat

**Mr. R. R. Shah**
Managing Director
**Mercury Laboratories Limited**
2/13-14, B.I.D.C, Industrial Estate,
Gorwa, Vadodara - 390 016, Gujarat

**Mr. Samir Shah**
Director
**OBOI Laboratories P Ltd / Ciron Drugs and Pharmaceuticals P. Ltd.**
1, Prabhat Nagar, Jogeshwari West,
Mumbai - 400 102

**Mr. Vijay Shah**
CMD
**Stallion Laboratories Pvt. Ltd.**
8th Floor, Devpath Complex Behind
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Ahmedabad - 380 006

**Mr. Vinod Kalani**
Promoter
**Cris Pharma (India) Ltd./**
**Oasis I-Tech Pvt. Ltd.**
SP-2, 22 Godown Industrial Area,
Jaipur 302 006

**CO-OPTED MEMBERS**

**Mr. Ajit Singh**
Chairman
**ACG Associated Capsules Pvt. Ltd.**
Dalamal House, 10th Floor, 1001,
Nariman Point, Mumbai - 400 021

**Mr. Bodh Raj Sikri**
Director
**ABS Mercantiles Pvt. Ltd.**
SCO – 313, 2nd Floor, Sector -29,
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**Dr. Azadar Khan**
Sr. Vice President
**Sun Pharmaceutical Laboratories Ltd**
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**Mr. K. Nithyananda Reddy**
Managing Director
**Aurobindo Pharma Ltd.**
Plot No. 2, Maitri Vihar,
Ameerpet, Hyderabad – 500 038

**Mr. Nikhil Chopra**
CEO & Whole Time Director
**J B Chemicals & Pharmaceuticals Limited**
8th Floor, Unit A, Cnergy IT Park, Appa Saheb
Marathe Marg, Prabhadevi, Mumbai - 400 025

**Mr. Pankaj R. Patel**
Chairman
**Zydus Lifesciences Limited**
Zydus Corporate Park, Scheme No. 63,
Survey no. 536, Khoraj (Gandhinagar),
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**Mr. Prashant Kumar Tewari**
Managing Director
**USV Private Limited**
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**Mr. Premchand Godha**
Executive Chairman
**IPCA Laboratories Limited**
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**SPECIAL INVITEES**

**Mr. Abhinav Arora**
Managing Director
**Synokem Pharmaceuticals Ltd.**
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**Mr. Ajay Agarwal**
Executive Director
**Macleods Pharmaceuticals Ltd.**
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**Mr. Ajit Kumar Jain**
Joint Managing Director
**IPCA Laboratories Ltd.**
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CTS No.328,
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**Mr. Ankur Heramb Joshi**
Director
**Eisen Pharmaceutical Co. Pvt. Ltd.**
34 / 7, Erandwana
Pune 411 004

**Mr. Ankur Vaid**
Joint Managing Director & CEO
**Concord Biotech Limited**
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**Mr. Atul Parab**
Associate Vice President &
Head Sales HR,
(India Branded Business)
**Alkem Laboratories Ltd.**
Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai - 400 013

**Mr. Bharat R. Desai**
Chairman & Managing Director
**Bharat Parenterals Ltd.**
Survey No. 144A, Haripura, Taluka-Savli,
District - Vadodara - 391 520, Gujarat

**Mr. Bhupendra H. Sangani**
Managing Director
**Galentic Pharma (India) Pvt. Ltd.**
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**Mr. Chinmaya Mohanty**
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**Dr. Amit Rangnekar**
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**Dr. Darshan Kataria**
*Managing Director*
**Vindas Chemical Industries P. Ltd.**
Indore, Madhya Pradesh, India

**Dr. Dinesh Dua**
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*Jt. Managing Director*
Aarti Drugs Ltd.
Mahendra Industrial Estate, Ground Floor, Plot No. 109-D, Road No. 29, Sion East,
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**Mr. Jayant Dwivedy**
*Executive Director & COO*
**USV Private Limited**
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**Mr. K. Raja Bhanu**
*Director General*
**Pharmaceuticals Export Promotion Council of India (PHARMEXCIL)**
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**Mr. Kunal Narendra Gandhi**
*Managing Director*
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*Jt. Managing Director*
**Troikaa Pharmaceuticals Limited**
'Commerce House-1', Satya Marg,
Bodakdev, Ahmedabad - 380 054,
Gujarat

**Mr. Mohan Babulal Jain**
*Director*
**Naprod Life Sciences Pvt. Ltd.**
304, Town Centre 1, Andheri-Kurla Road, Andheri East, Mumbai 400 059

**Mr. Nikhil Jitendra Shah**
*Director*
**Marvel Drugs Pvt. Ltd.**
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Churchgate, Mumbai - 400 020

**Mr. Niraj M. Doshi**
*CEO*
**Dy-Mach Pharma**
B-12 Anand Sagar, Old Nagardas Road, Andheri (E), Mumbai - 400 069

**Mr. Paresh Mehta**
*Managing Director*
**Intermed Laboratories Pvt. Ltd.**
A/3, Todi Industrial Estate, Sunmill Compound, Lower Parel (W),
Mumbai - 400 013

**Mr. Prakash Mudda**
*President – Corporate Projects & Operations*
**Micro Labs Limited**
#58C/12, Kudlu Main Road,
Off. Hosur Road, Kudlu,
Bangalore - 560 068, India

**Mr. S. M. Mudda**
*Managing Director*
**Misom Labs Limited**
Malta Life Sciences Park
I.S2.01.06, Industrial Estate
San Gwamn, SGN 3000, Malta

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

**Mr. Sahil Munjal**
*Director*
**Ind Swift Laboratories Ltd.**
SCO 850, NAC, Manimajra,
Chandigarh - 160 101

**Mr. Samita H. Aiyer**
*Director*
**Somatico Pharmacal Pvt. Ltd.**
Plot No. C-469, MIDC, Pawane,
Navi Mumbai 400705 & Plot No. 100,
Sector-8, Vashi, Navi Mumbai - 400 703

**Mr. Sanchit Kaushik Chaturvedi**
*Managing Director*
**Halewood Laboratories Pvt. Ltd.**
310, Sankalp Square-2, Near Jalaram
Temple, Paldi, Ahmedabad,
Gujarat - 380 006

**Mr. Sandeep Singh**
*Managing Director*
**Alkem Laboratories Ltd.**
Alkem House, Senapati Bapat Marg,
Lower Parel West, Mumbai - 400 013

**Mr. Satish Kumar Singh**
*Managing Director*
**Cachet Pharmaceuticals Pvt. Ltd.**
415, Shah & Nahar, industrial Estate,
Dr E Moses Road, Worli,
Mumbai - 400 018

**Mr. Sharvil Pankajbhai Patel**
*Managing Director*
**Zydus Lifesciences Ltd.**
Zydus Corporate Park, Scheme No. 63, Sur-
vey No. 536, Nr. Vaishnoydevi Circle,
Ahmedabad - 382 481

**Mr. Shiv Sagar Tewari**
*Co-Managing Director*
**Burnet Pharmaceuticals (P) Ltd.**
Regd Off- 28/5, C N Roy Road,
Kolkata - 700039

**Mr. Sumit Agrawal**
*Partner*
**Ishita Pharmaceuticals**
401, 3rd Eye Two, Opposite Parimal Garden,
Ellisbridge, Ahmedabad - 380 006

**Mr. Sumit Singla**
*Managing Director*
**Curetech Formulations Pvt. Ltd.**
Vill Juddi Kalan Baddi, Distt Solan,
HP - 173 205

**Mr. Sundeep Vasant Bambolkar**
*Joint Managing Director*
**Indoco Remedies Ltd.**
Indoco House, 166 CST Road, Kalina,
Santacruz (East), Mumbai - 400 098

**Mr. Vasudev Kataria**
*Director*
**Vindas Chemical Industries Pvt. Ltd.**
210, Adamji Building, 413, Narsi Natha Street,
Masjid Bandar (W), Mumbai - 400 009

**Mr. Vijay Dalvi**
*Head - HR & Admn*
**Blue Cross Laboratories (P) Ltd.**
Peninsula Chambers,
Ganpatrao Marg
Lower Parel, Mumbai - 400 013

**Mr. Vishal Narayanprasad Jajodia**
*Managing Director*
**Swati Spentose Pvt. Ltd.**
114, Marine Chambers, 11 New Marine Lines,
Mumbai - 400 020

**Mr. Vishwanath Swarup**
**GlaxoSmithKline Pharmaceuticals Limited**
GSK House
252, Dr. Annie Besant road, Worli,
Mumbai 400 030

**Mr. Yashwant C. Patel**
*CMD*
**Elysium Pharmaceuticals Ltd.**
Post: Dabhasa, Tal. Padra Dist.
Vadodara,Gujarat - 391 440

## PAST NATIONAL PRESIDENTS

**Dr. Abraham A. Patani, D.Sc.**
*(Founder Secretary) C.M.D.*
**INGA Laboratories P. Ltd.**
Inga House, Mahakali Road,
Andheri East, Mumbai - 400 093

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

**Dr. Dinesh S. Patel**
*Chairman*
**Themis Medicare Limited**
11/12, Udyog Nagar, S. V. Road,
Goregaon (West), Mumbai - 400 104

**Dr. Gopakumar G Nair**
*CEO*
**GNANLEX Group**
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Kandivli (East), Mumbai - 400 101

**Mr. Nihchal H. Israni**
*Chairman*
**Blue Cross Laboratories Pvt. Ltd.**
Peninsula Chambers, G.K. Marg,
Lower Parel (W), Mumbai - 400 013

**Mr. Yogin Majmudar**
*Managing Director*
**Bakul Aromatics And Chemicals Pvt. Ltd.**
Sterling Centre, Dr. A. B. Road,
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**Mr. Suresh G. Kare**
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**Indoco Remedies Ltd.**
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**Mr. Manish Doshi**
*Managing Director*
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**Mr. B. N. Singh**
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Lower Parel (W), Mumbai - 400 013

**Mr. Navrattan Munjal**
*Chairman & Managing Director*
**Ind Swift Laboratories Limited**
SCO-850, Shivalik Enclave,
NAC, Manimajra, Chandigarh - 160 101

**Dr. S. V. Veeramani**
*Chairman & Managing Director*
**Fourrts (India) Laboratories Pvt. Ltd.**
1, Fourrts Avenue, Annai Indira Nagar,
Okkiyam Thoraipakkam, Chennai - 600 097

**Mr. Deepnath Roy Chowdhury**
*Managing Director*
**Strassenburg Pharmaceuticals Pvt. Ltd.**
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**Mr. Mahesh H. Doshi**
*Partner & Managing Director*
**DY-MACH Pharma**
B-12, Anand Sagar, Old Nagardas Road,
Andheri (E), Mumbai - 400 069

**EX-OFFICIO MEMBER**

**Mr. Pranav Choksi**
*CEO*
**Gufic Biosciences Ltd.w**
S.M. House, 11 Sahakar Road, Vile Parle
(East) Mumbai - 400 057

**Mr. Vinay Pinto**
*Executive Director*
**Wallace Pharmaceuticals Pvt. Ltd.**
WALLACE TOWERS, 5th floor, 139-140/B/1,
Western Express Highway, Vile Parle (E),
Mumbai - 400057

**CORPORATE MEMBER**

**Mr. Ajay Bhardwaj**
*Founder & Chief Executive Officer*
**Anthem Biosciences Limited**
No. 49, F1 & F2, Canara Bank Road,
Bommasandra Industrial Area, Phase- I,
Bommasandra, Bangalore – 560 099,
Karnataka

**Mr. Ajay Kumar Desai**
*Sr Vice President*
**Alembic Pharmaceuticals Limited**
2nd Floor, Prime Corporate Park, Behind ITC
Grand Maratha-Sheraton, Sahar Road,
Andheri (East), Mumbai - 400 099

**Mr. Arjun Juneja**
*Chief Operating Officer*
**Mankind Pharma Ltd.**
208, Okhla Industrial Estate, Phase-III,
New Delhi - 110 020

**Mr. Ashok Nair**
*Managing Director*
**RPG Life Sciences Ltd.**
RPG House, 4th Floor, 463, Dr. Annie Besant
Road, Worli, Mumbai - 400 030

**Mr. Dheer Dharmesh Shah**
*Executive Director*
**BDR Pharmaceuticals International Pvt. Ltd.**
6, Engineering Centre, 9, Mathew Road,
Opera House, Mumbai - 400 004, India

**Dr. (Ms.) Satya Ramani Vadlamani**
*Chairperson and Managing Director*
**Murli Krishna Pharma Pvt. Ltd.**
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Pune - 412 209

**Dr. Arif A. Faruqui**
*Senior Vice President-*
*Medical Services*
**Medley Pharmaceuticals Ltd.**
Medley House, D2, 16th Road, MIDC,
Andheri (East), Mumbai - 400 093

**Dr. Kalpana J. Bhatwadekar**
*Director*
**Sirmaxo Chemicals Pvt. Ltd.**
5th Floor, Satyanarayan Prasad Commercial
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Vile Parle (E), Mumbai - 400 057

**Dr. R. Arul**
*President and COO API and CDMO*
**Jubilant Pharmova Ltd.**
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**Dr. Satyanarayana Chava**
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**Mr. J. J. Shah**
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**Mr. Jinesh Shah**
*Director*
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**Mr. Mohal Sarabhai**
*CEO*
**Asence Pharma Pvt. Ltd.**
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**Mr. Mohan Rayana**
*Group Head*
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BSEL Tech Park, B-Wing, 10th Floor,
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**Mr. Narender Kukreja**
*Managing Director*
**M/s Mascot Health Series Pvt Ltd**
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**Mr. Nikkhil K. Masurkar**
*Chief Executive Officer*
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**Mr. Pranav Shah**
*Chairman*
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**Mr. Raja Sekhar Vanga**
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**Mr. Rajeev Nannapaneni**
*Vice Chairman & CEO*
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**Mr. Sanjay M. Sakaria**
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**Mr. Sanjeev Jain**
*Chairman*
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**Mr. Sanjeev Kumar**
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**Mr. Satish Reddy Kallam**
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**Mr. Shriram Balasubramanian**
*Director Commercial and*
*Business Development*
**Zuventus Healthcare Ltd**.
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**Mr. Siddharth Mittal**
*CEO & Managing Director*
**Biocon Limited**
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**Mr. Sohan Dadhich**
*Managing Director*
**KLM Laboratories Pvt. Ltd.**
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Udhana Darwaja Surat 395 002, Gujarat, India

**Mr. Sudhir Vaid**
*Chairman & Managing Director*
**Concord Biotech Limited**
16th Floor, B-Wing, Mondeal Heights,
Iskon Cross Road, S.G. Highway,
Ahmedabad - 380 015, Gujarat

**Mr. T. Sathish**
*Vice President - Regulatory & Corporate Support*
**Tablets India Limited**
Jhaver Centre, 4th Floor, No. 72,
Marshalls Road, Egmore, Chennai - 600 008

**Mr. Vipul Gupta**
*Vice President and Head-Corporate Affairs and Policy*
**Cipla Limited**
10th Floor, 28, Barakhamba Road, Gopaldas Building, Connaught Place, New Delhi - 110 001

**Mr. Viral Shah**
*Managing Director & CEO*
**ACME GROUP**
(ACME Formulation Private Limited/ ACME Generics Private Limited and Immacule Life-sciences Private Limited)
Village-Chowkiwala, Ropar Road,
Nalagarh, Dist. Solan, HP-174 101, India

**Mr. Bhahim Bharatkumar Desai**
*Director*
**INNOXEL LIFESCIENCES PRIVATE LTD.**
Survey No.144/146, P.O. Haripur
Ta: Savli, Dist : Vadodara
Gujarat – 391520

**Mr. B.B. Mohankumar**
*Director*
**EAST WEST PHARMA INDIA PVT LTD**
Door No.4/1, 2nd floor, Itteri Road
Ayyamperumapatty, Adivara Road,
Near Law College Bus Stop,
Kannakuruchi, Salem – 8 Tamil Nadu

**Mr. Gopal Agrawal**
*Director*
**ANUPAM RASAYAN INDIA LIMITED**
10th floor, Icon rio, Behind Icon Business Centre, Dumes Road,
Surat - 395007
Gujarat

**Patron Members**

**Dr. Vivekanand V. Palkar**
*Chairman & Managing Director*
**Nivedita Chemicals Pvt. Ltd.**
Anek Prayog Pvt. Ltd.
A-14, M.I.D.C., Andheri (E), Mumbai - 400 093

**Ms. Jayashree Nair**
*Managing Director*
**BDH Industries Limited**
Nair Baug, Akurli Road, Kandivali (E),
Mumbai - 400 101 Tel. :(B) 022-61551234

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

**Mr. Kushal Shah**
*General Manager*
**Acichem Laboratories**
1, Prabhat Nagar, Jogeshwari (W),
Mumbai - 400 102

**Mr. Nirmal Lalchand Jain**
*Partner*
**Nirlac Chemicals**
14th Floor, Nirmal Building,
Nariman Point, Mumbai - 400 021

**Mr. Sachin Chandrakant Gandhi**
*Director*
**Vital Healthcare Pvt. Ltd.**
5/6, Shreyas, 2nd Hasnabad Lane,
Santacruz (W), Mumbai - 400 054

## GUJARAT STATE BOARD

***Chairman***

**Mr. Sanchit Kaushik Chaturvedi**
Managing Director
**Halewood Laboratories Pvt. Ltd.**
310, Sankalp Square-2, Near Jalaram
Temple, Paldi, Ahmedabad
Gujarat - 380006

***Hon. Secretary***

**Mr. Harpal Vala**
Managing Director
**Kepler Healthcare Pvt. Ltd.**
9, Solitaire Sky, Beside Hyatt Regency,
Ashram Road, Ahmedabad – 380014

***Executive Secretary***

**Mr. J. D. Raval**
Executive Secretary
**IDMA – GSB**
4, Park Avenue, 1st Floor, Parimal Garden
Cross Road, Opp. RBL Bank, Ellisbridge,
Ahmedabad – 380 006

## TAMIL NADU, KERALA, PUDUCHERRY STATE BOARD

***Chairman***

**Mr. J. Jayaseelan**
*Managing Director*
**Sai Mirra Innopharm Pvt. Ltd.**
No. 5/A5, Third Cross Road, IT Park,
Siruseri, Chennai - 603 103

***Hon. Secretary***

**Mr. S Sivanandhan**
*Managing Director*
**Ceego Labs Pvt. Ltd.**
23/6, Dr. Ambedkar Road, 1st Floor,
Kodambakkam Road,
Chennai – 600024

| | |
|---|---|
| ***Executive Secretary*** | **Mr. Kannan Krishnan**<br>*Executive Secretary*<br>**IDMA, Tamil Nadu, Puducherry & Kerala State Board**<br>Block D1, "Baid Metha Complex", No. 16, AnnaSalai, Little Mount, Saidapet, Chennai - 600 015 |

**WEST BENGAL STATE BOARD**

| | |
|---|---|
| ***Chairman*** | **Mr. Shiv Sagar Tewari**<br>*Co-Managing Director*<br>**Burnet Pharmaceuticals (P) Ltd.**<br>Regd Off- 28/5, C N Roy Road, Kolkata-700 039, Corporate Off.- Lodha Supremus Business Park 508, B-Wing, Thane, Maharashtra - 400 607, India |
| ***Hon. Secretary*** | **Mr. Siddhartha Paul**<br>*Executive Director*<br>**Palsons Derma Pvt. Ltd.**<br>10/D/1, Ho-Chi-Minh Sarani, Kolkata - 700 071 |

**KARNATAKA STATE BOARD**

| | |
|---|---|
| ***Chairman*** | **Mr. S. M. Mudda**<br>Managing Director<br>**Misom Labs Limited**<br>Malta Life Sciences Park, LS2.01.06, Industrial Estate, San Gwann, SGN3000, Malta |
| ***Hon. Secretary*** | **Mr. Prakash Mudda**<br>*President – Corporate Projects & Operations*<br>**Micro Labs Limited**<br>#58C/12, Kudlu Main Road, Off. Hosur Road, Kudlu, Bangalore – 560 068. |

**HIMACHAL PRADESH & UTTARAKHAND STATE BOARD**

| | |
|---|---|
| ***Chairman*** | **Mr. R. C. Juneja**<br>*Chairman*<br>**Mankind Pharma Ltd.**<br>208, Okhla Industrial Estate Phase-III,<br>New Delhi - 110 020 |

| | |
|---|---|
| ***Hon. Secretary*** | **Mr. Bodh Raj Sikri**<br>*Director*<br>**ABS Mercantiles Pvt. Ltd.**<br>Sco – 313, 2nd Floor, Sector -29,<br>Gurgoan - 122009 |

**MADHYA PRADESH STATE BOARD**

| | |
|---|---|
| ***Chairman*** | **Mr. Paresh Chawla**<br>*Managing Director*<br>**ALPA Laboratories Limited**<br>33/2 Pigdamber, A.B. road, Rau, Indore<br>M.P. - 453 446 |
| ***Hon. Secretary*** | **Mr. Anil Kumar Sabrahwal**<br>*Chairman & Managing Director*<br>**Quest Laboratories Limited**<br>Plot No. 45, Opp. Kissan Pipe Unit 4,<br>Sector III, Pithampur<br>Dist. Dhar (M.P.) - 454 775 |

**TELANGANA STATE BOARD**

| | |
|---|---|
| ***Chairman*** | **Mr. K. V. Rambabu**<br>*Managing Director*<br>**Pulse Pharmaceuticals Pvt. Ltd.**<br>Plot No. 18/1, Sector III,<br>Huda Techno Enclave,<br>HITEC City Hyderabad,<br>Telangana - 500 081, India |
| ***Hon. Secretary*** | **Mr. I. R. Sekhar Rao**<br>*Managing Director*<br>**Therdose Pharma Pvt. Ltd.**<br>118 - 120, Road No.6, Kukatpally, ALEAP<br>Industrial Area, Pragathi Nagar, Hyderabad,<br>Telangana 500 090, India |

**HARYANA STATE BOARD**

| | |
|---|---|
| ***Hon. Secretary*** | **Mr. T. C. Kansal**<br>*Managing Director*<br>**Crystal Pharmaceuticals**<br>365, Model Town,<br>Ambala City - 134 003, Haryana, India |

# LIST OF IDMA COMMITTEES, CHAIRPERSONS & VICE CHAIRPERSONS FOR THE YEARS 2025 & 2026

| S. No. | COMMITTEES | CHAIRPERSON | VICE CHAIRPERSON |
|---|---|---|---|
| 1. | Biotech | **Dr. Jaby Jacob**<br>Bharat Serums & Vaccines Ltd. | **Devesh Malladi**<br>Embio Ltd. |
| 2. | Bulk Drugs | **Yogin Majmudar**<br>Bakul Aromatics And Chemicals Pvt. Ltd. | **Bipin Shah**<br>Anuh Pharma<br>**Neha Thakore**<br>Avik Pharmaceuticals Ltd. |
| 3. | Contract Manufacturing | **Abhinav Arora**<br>Synokem Pharmaceuticals Ltd. | **Mehul Shah**<br>Encube Ethicals Pvt. Ltd. |
| 4. | Digital Initiatives | **Kamlesh Patel**<br>West-Coast Pharmaceutical Works Ltd. | **Vivek Shah**<br>S Kant Healthcare |
| 5. | Employees Relations and Development | Advocacy Group<br>• **Atul Parab,** Alkem Laboratories Ltd.<br>• **Vijay Dalvi**, Blue Cross Laboratories Pvt. Ltd.<br>• **Chinmay Mohanty,** Wallace Pharmaceuticals | |
| 6. | ESG | **Neha Thakore**<br>Avik Pharmaceuticals Pvt. Ltd. | **Mansi Kampani**<br>Encube Ethicals Pvt. Ltd. |
| 7. | Excise and Taxation | **B. G. Barve**<br>Blue Cross Laboratories Pvt. Ltd. | **Ketki Wadhawa**<br>Blue Cross Laboratories Pvt. Ltd. |
| 8. | Finance and Administration | **Mehul Shah**<br>Encube Ethicals Pvt. Ltd. | **B. G. Barve**<br>Blue Cross Laboratories Pvt. Ltd. |
| 9. | Industry Institutes Interaction | **Dr. Shrenik Shah**<br>Montage Laboratories Pvt. Ltd. | **Dr George A Patani,**<br>INGA Laboratories P. Ltd.<br>**Probhas Bondhu Chakraborty,** Mendine Pharmaceuticals Pvt. Ltd. |
| 10. | International Trade (Incl. Customs) | **Sundeep Bambolkar**<br>Indoco Remedies Pvt. Ltd. | **Bhavin Mehta**<br>Kilitch Co. (Pharma) |

| | | | |
|---|---|---|---|
| 11. | IPR | **Dr. Gopakumar G Nair**<br>Gopakumar Nair & Associates | **Smita Prajapati**<br>FDC Ltd. |
| 12. | Marketing | **Vishwanath Swarup**<br>GlaxoSmithKline Pharmaceuticals Limited | |
| 13. | Medical | **Dr. Mahesh Abhayankar**<br>Glowderma Labs Pvt. Ltd. | **Dr. Abhijit Trailokya**<br>Indoco Remedies Ltd. |
| 14. | Membership and Constitution | **Mahesh Doshi**<br>Dy-Mach Pharma | **Chirag Doshi**<br>Yash Medicare Pvt. Ltd. |
| 15. | MSME | **S R Vaidya**<br>Kremoint Pharma Pvt. Ltd. | **Dr. Lakshmanan Ramaswamy**<br>Sotax India |
| 16. | NDPS | **Devesh Malladi**<br>Embio Ltd. | **Neetta Mohit**<br>Abbott Healthcare |
| 17. | Next Gen | **Niraj Doshi**<br>Dy-Mach Pharma | **Darpan Roy Chowdhury**<br>Strassenburg Pharmaceuticals<br>**Kunal Gandhi**<br>Lyka Labs Ltd. |
| 18. | Nutraceuticals | **Dr R K Sanghavi**<br>Seagull Pharmaceuticals Pvt. Ltd. | **Ganesh V Kamath**<br>Vital Nutraceutials |
| 19. | PR | **J Jayaseelan**<br>Sai Mirra Innopharm Pvt. Ltd. | **J Rajamouli**<br>EuroMedicare Int'l |
| 20. | Pricing / Consumer Affairs | **Dr. Amit Rangnekar**<br>Centaur Pharmaceuticals | **C V Venkataraman**<br>Lupin Ltd. |
| 21. | Publications | **Dr. George A Patani**<br>INGA Laboratories Pvt. Ltd. | **Dr Nagraj Rao**<br>RRR Labs Pvt. Ltd. |
| 22. | Quality Management and Technical | **Dr. Vinay G Nayak**<br>Aarti Pharmalabs Ltd. | **Dr Milind Joshi**<br>Ramnarain Ruia College |
| 23. | R & D and Innovation | **Sanjiv Navangul**<br>Bharat Serums & Vaccines | **Nikkhil K Masurkar**<br>Entod Pharmaceuticals |
| 24. | Regulatory Affairs | **S M Mudda**<br>Misom Labs Ltd. | **S W Deshpande**<br>Pharmalex |

# SECRETARIAT

## HEAD OFFICE (MUMBAI)
## INDIAN DRUG MANUFACTURERS' ASSOCIATION

102, A Wing, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai – 400018,
Maharashtra, India.
Tel No.: 91-22-49729227 / 66626901

**DAARA B PATEL**
*Secretary-General*
Email : **daara@idmaindia.com**

**SAPNA PATIL**
*Deputy Secretary-General*
Email : **sapna@idmaindia.com**

**MELVIN P RODRIGUES**
*Assistant Secretary-General*
Email : **melvin@idmaindia.com**

## DELHI OFFICE

2nd Floor, B – 4/115, Safdarjang Enclave, New Delhi – 110029.
Tel. : +91-11-26171367 / 41650726

**ASHOK KUMAR MADAN**
*Executive Director*
Email: **akmadan.idma@gmail.com**

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

# 64th Annual Report 2025

*Dear Members,*

*I am pleased to present the 64th Annual Report of our esteemed Association – the Indian Drug Manufacturers' Association (IDMA).*

*The year commenced with Mr. Bharat N Shah taking over from Dr. Viranchi Shah as the 27th National President of IDMA. The theme for the year* ***"Innovating Today for a Healthier Tomorrow"*** *aptly captures the spirit and aspirations of the Indian Pharmaceutical Industry. This theme has been thoughtfully conceived for IDMA members inspiring them to foster innovation while enabling sustained growth, excellence and long-term prosperity.*

*Under the leadership of Mr. Bharat N. Shah who was ably supported by Dr. George A. Patani - Senior Vice President, Ms. Aditi Kare Panandikar - Hon. General Secretary and the 24 Chairpersons of various IDMA Committees, the Association witnessed a dynamic, impactful and meaningful progress during the year. Strong and dedicated support from Senior Members such as Dr. Viranchi Shah, Mr. Mehul Shah, Past national Presidents, State Boards Chairmen and various members enabled IDMA to actively participate in* ***154 meetings and submit 95 representations****, firmly establishing its role as a leading and influential* ***Voice of the Indian pharmaceutical industry.***

### *PHARMACORE INDIA - IDMA & MESSE MUNCHEN INDIA*

*Mr. Bharat Shah mentioned that a Memorandum of Understanding (MoU) between the Indian Drug Manufacturers' Association (IDMA) and Messe Muenchen India was signed on 26th August 2025 to jointly organize PHARMACORE INDIA 2026 a premier trade fair dedicated to advancing India's pharmaceutical ecosystem.*

*PHARMACORE INDIA 2026 is scheduled to be held from 22nd to 24th April 2026 at the Jio World Convention Centre, Mumbai. The event will be positioned as Western India's exclusive strategic marketplace for key pharmaceutical segments, including formulations, chemicals and excipients, and active pharmaceutical ingredients (APIs). This initiative aims to create a strong industry platform for collaboration, innovation, and business growth within India's pharma value chain.*

### *IDMA 63rd Annual General Meeting*

*Dr. Viranchi Shah's farewell speech at the 63rd Annual General Meeting perfectly captured his transformative leadership. He reflected on his impactful presidentship (2022–2024) wherein he began his term with the guiding* ***RITE*** *framework:* ***Regulatory Reforms, Innovation, Team Building, and Entrepreneurship.*** *After an exceptionally successful tenure, he handed over a legacy defined by a new* ***RITE: Reach, Impact, Trust, and Engage & Win-Win****. This development*

*underscores Dr. Shah's success in building bridges with Government, Regulators and IDMA members alike, fostering trust and mutual gains that strengthened the Association.*

*Mr. Bharat N. Shah, Managing Director of S. Kant Healthcare Ltd. commenced his National President (2025–2026) at IDMA with* ***STRIDE*** *— a strategic roadmap for excellence:* ***Supply Chain Resilience, Technological Advancements, Regulatory Reforms, Innovation, Digital Initiatives, and Environmental Sustainability****. Building on Dr. Viranchi Shah's RITE legacy, Mr. Shah's framework emphasizes a foundation promising robust growth for IDMA members and the industry.*

*Mr. Bharat N. Shah, National President, announced that IDMA would henceforth have 24 Committees and proudly introduced two new Committees, namely the* ***Biotech Committee*** *and the* ***Next Gen Committee****. The Next Gen Committee was envisioned to bring together the next generation of entrepreneurs who would play a pivotal role in IDMA's activities and initiatives. The Next Gen Committee received blessings at the auspicious hands of Mr. Piyush Goyal, Hon'ble Union Minister of Commerce and Industry, marking a significant milestone in nurturing future leadership within IDMA.*

***IDMA 63rd Annual Day Celebrations***

*IDMA 63rd Annual Day celebrations was held on Saturday, 8th February 2025 at Crystal Room, Hotel Taj Mahal Palace, Opp. Gateway of India, Mumbai. The celebrations were graced by* ***Chief Guest - Honourable Shri Piyush Goyal, Minister of Commerce & Industry****, Special Guest of Honour –* ***Smt. Anupriya Singh Patel, Hon'ble Minister of State for Health & Family Welfare and Chemicals & Fertilizers****, Guest of Honour -* ***Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India),*** *Keynote Address -* ***Dr. Habil Khorakiwala, Founder Chairman of Wockhardt****. The celebrations were also graced by* ***Dr. Yusuf Hamied of Cipla,*** *alongside the distinguished leaders of the Indian Pharmaceutical Industry. Their esteemed presence elevated the celebrations, which witnessed participation from over 400 participants including TV & Press attendees. Bain & Company released their report "****Healing the World: Roadmap for Making India a Global Pharma Exports Hub".*** *The report is authored by Sriram Shrinivasan, Rohit Singh and Anik Ganguly and is written in collaboration between Bain & Company, IDMA, Indian Pharmaceutical Alliance (IPA) and Pharmexcil. The Report was released by Shri Piyush Goyal, Union Minister of Commerce and Industry.*

***Investor States Meetings***

*During the year, IDMA actively engaged with key investor-friendly states including Chhattisgarh, Himachal Pradesh, Odisha and Madhya Pradesh. These meetings provided a constructive platform to interact with State Governments, understand policy frameworks, explore investment opportunities and discuss industry-related concerns. The interactions showcased IDMA's commitment to its members across India by supporting collaborative growth and enhancing the pharmaceutical industry across these states.*

***Meeting of Office Bearers & Committee Chairpersons***

*Mr. Bharat Shah presided over the first meeting (hybrid) of the Office Bearers and Committee Chairpersons on Friday, 14th February 2025. Almost all the Office Bearers as well as the Chairpersons attended the meeting and presented their committee plans for the year. Mr. Bharat Shah mentioned the importance of commitment and active participation from all committee chairpersons and encouraged them to go beyond just fulfilling their responsibilities as their efforts are vital in effectively representing the pharmaceutical industry. He confirmed his support and assured them that IDMA Secretariat would fully support their initiatives and activities.*

***USP Convention 2025***

*Mr. Daara B Patel attended his fourth USP Convention Week from May 5–8, 2025, in Rockville, Maryland, USA as an Observer. He also attended the 5th South Asia Regional Chapter Meeting on May 8, 2025 at Linden Oak, Marriott Hotel, Rockville. He took active part in the below three Resolutions :*

- *Resolution I: Foster Greater Availability of the World's Most Utilized Medicines*
- *Resolution IV: Advance Quality Through the Increased Use of Digital Technologies*
- *Resolution VII: Help Strengthen Regulatory Systems Around the World*

*The USP Convention was duly supported by many Government Officials, Heads of other Associations in India and technical experts from India.*

***MHRA India - Visit of UK MHRA with British High Commission Representatives***

*IDMA held meetings with representatives from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the British High Commission in both Delhi and Mumbai. The UK delegation comprised Mr. James Pound, Interim Executive Director – Innovation and Compliance; Ms. Emanuela Krasteva, Lead Senior GDP Inspector; and Mr. Trevor Watson, Lead Senior GMP Inspector. The meetings were coordinated by Dr. Himangi Bhardwaj, MBE, Head – Health and Life Sciences. The IDMA delegation was led by Ms. Aditi Kare Panandikar, Hon. General Secretary. During the interactions, Mr. James Pound spoke at length on enhancing regulatory collaboration between the UK and India, while Mr. Trevor Watson addressed and clarified the issues and observations raised during the discussions. IDMA also placed before the delegation a consolidated list of concerns and suggestions compiled from its member companies.*

***Withdrawal of Track and Trace system for export of drug formulations***

*Mr. Daara Patel mentioned that the Directorate General of Foreign Trade (DGFT), vide Public Notice No. 44/2024–25 dated 31st January 2025, has withdrawn Para 2.76 of the Handbook of Procedures 2023 relating to the Track and Trace system for the export of drug formulations, with immediate effect. He further stated that the implementation of the Track and Trace system will*

*now be undertaken by the Ministry of Health & Family Welfare in accordance with the provisions of the Drugs Rules, 1945. IDMA expressed its gratitude to the Hon'ble Minister Shri Piyush Goyal and acknowledged the significant contribution of Mr. Mehul Shah who played a pivotal role in achieving this outcome.*

***White Paper on US Tariff Plan and their Implications for the Indian Pharmaceutical Industry***

*Mr. Daara Patel mentioned that IDMA had prepared a White Paper on the proposed US Tariff Plan and its potential impact on the Indian pharmaceutical industry, in response to a request received from the Department of Commerce vide its email dated 11th February 2025. The Department had sought inputs on the Reciprocal Tariff announced by the United States on pharmaceutical products. Accordingly, IDMA submitted the White Paper to the Department of Commerce on 27th February 2025, incorporating valuable insights and inputs from Mr. Mehul Shah and Mr. Sundeep Bambolkar. Ms. Aditi Kare Panandikar further elaborated that the White Paper highlighted key challenges arising from reciprocal tariffs and drew attention to potential tariff revisions as well as certain non-tariff barriers that are often overlooked. She emphasized that the document underscored the need to address and eliminate such barriers to ensure fair and balanced trade.*

*Mr. Bharat Shah observed that the introduction of a reciprocal tariff regime could significantly impact business operations and trade dynamics. He expressed hope that the Government would take these considerations into account while formulating any changes to tariff policy.*

***IDMA's Executive Committee Meeting at Encube Ethical's Advanced Research Centre, Pallava, Mumbai***

*Mr. Bharat Shah mentioned that the Fourth Executive Committee was held at the state-of-the-art facility of Encube Ethical's Advanced Research Centre. Mr. Bharat Shah thanked and appreciated Mr. Mehul Shah for the excellent arrangements and for organizing a comprehensive tour of the research centre.*

***Revised Export NOC Guidance document for Manufacture of Unapproved / Approved New Drugs along with revised Annexures***

*Dr. Viranchi Shah mentioned that CDSCO has issued a revised guidance document on 7th May 2025 for the issuance of Export No Objection Certificates (NOC) for unapproved and approved new drugs meant solely for export purposes.*

*He said that the Key changes include:*

- *Discontinuation of quantity-specific and purchase order-specific NOCs, except for NDPS and banned drugs.*
- *Centralization of NOC issuance—now solely under CDSCO Zonal Offices effective May 15, 2024.*

- *Powers earlier vested with State/UT Licensing Authorities have been withdrawn.*

*All past NOCs (from 20 Aug 2018 to 14 May 2024) are to be transferred to respective CDSCO zonal offices for record.*

***10th Edition of Pharmac South- Pharma Exhibition***

*Mr. Daara Patel mentioned that the IDMA Tamil Nadu, Puducherry & Kerala State Board successfully organized the 10th Edition of Pharmac South on Friday, 4th July 2025, at the Chennai Trade Centre. He said that this flagship event showcased the latest, most innovative and cost-effective technologies in pharmaceutical and nutraceutical manufacturing. Over the years, Pharmac South has emerged as a key platform for industry stakeholders to explore advancements, share knowledge and foster business collaborations. Mr. J. Jayaseelan, Chairman, IDMA TNPK State Board, expressed his sincere gratitude to the National President, the IDMA Secretariat, members and industry stakeholders for their active participation and support in making the 10th Edition a grand success and a valuable platform for networking and learning.*

***Meeting with U.S. Deputy Assistant Secretary for India***

*Mr. Daara Patel mentioned that Ms. Bethany Morrison, U.S. Deputy Assistant Secretary in the Bureau of South and Central Asian Affairs (India and Bhutan), visited Mumbai on 8th July 2025 and had a meeting with senior representatives of IDMA to discuss potential areas of collaboration between the U.S. and Indian pharmaceutical sectors. He said that the focus of the discussions included strategies for enhancing supply chain resilience for key active pharmaceutical ingredients (APIs) critical to both U.S. and Indian healthcare systems, exploring opportunities for Indian pharmaceutical investments in the United States, and advancing shared strategic objectives to mitigate shortages of essential medicines. IDMA proposed a strategic manufacturing framework that builds upon India's strengths in API production and backward integration. The framework emphasized the need for financial viability through mechanisms such as a one-time capital grant and concessional long-term loans to support cost-effective API manufacturing that is independent of Chinese inputs a viable "China +1" alternative. IDMA outlined a "Make in India, Stock in USA" model, advocating for U.S. FDA-compliant production facilities in India coupled with strategic stockpiling of essential APIs in the United States. Indian manufacturers also expressed readiness to explore direct participation in U.S.-based API production units, contingent on long-term procurement commitments to ensure commercial sustainability. The U.S. delegation responded positively to IDMA's proposals and requested a copy of the earlier presentation made by Mr. Devesh Malladi on 5th June 2025. IDMA shared both the new strategic suggestions and the requested presentation made by Mr. Devesh Malladi with the U.S. Deputy Assistant Secretary on the same day, 8th July 2025.*

***Breakfast Roundtable with Governor Phil Murphy***

*IDMA members attended a Breakfast Roundtable Meeting on 24.09.2025 at Taj Colaba, Mumbai with the visiting New Jersey Delegation led by Hon. Governor Phil Murphy and First Lady*

*Tammy Murphy, accompanied by senior representatives from Choose New Jersey and the New Jersey India Centre. The interaction aimed to strengthen partnerships between Indian life sciences companies and the State of New Jersey, one of the world's leading hubs for pharmaceuticals and biotechnology. The discussions focused on global expansion opportunities, state-level support mechanisms and potential collaborative initiatives to enhance bilateral engagement in innovation, manufacturing, and research.*

***Meeting to discuss the fall in export of Indian Pharmaceutical products to USA as per latest GTRI report***

*Mr. Mehul Shah mentioned that the Department of Pharmaceuticals (DoP) had organized a virtual meeting to discuss the recent decline in Indian pharmaceutical exports to the USA, as highlighted in the latest GTRI report. The meeting was chaired by Mr. Vishal Vishwanath Nair, IES, Economic Adviser & Joint Secretary, DoP and conducted by Dr. Jaijit Bhattacharya, President, C-DEP. He mentioned that the decline observed in August 2025 was a temporary fluctuation rather than a sustained trend. During the meeting, industry representatives clarified that many Indian exporters had frontloaded their shipments to the US during April–May 2025, anticipating possible tariff changes and market volatility. This led to higher export numbers in the earlier months and a corresponding decline later, creating a misleading impression of an overall fall.*

*Mr. Mehul Shah stated that the industry emphasized the need to view export data holistically rather than focusing on month-to-month variations. IDMA had submitted a detailed two-year comparative analysis demonstrating that overall export performance to the USA has remained stable. There has been no significant fall when assessed over the complete period. He further mentioned that the delegation also gave certain recommendations from the RoDTEP perspective, suggesting that the scheme be revisited to ensure continued competitiveness of Indian exports. The Government has been extending RoDTEP benefits every six months, and the current validity now stands extended till 31 March 2026. Mr. Mehul Shah mentioned that there was nothing untoward in the temporary decline and that Indian pharmaceutical exports to the US remain steady overall. Mr. Nair appreciated the industry's inputs and requested submission of written recommendations outlining key issues, short and long-term solutions and potential implementing agencies.*

***Launch of Anusandhan National Research Foundation (ANRF)***

*Anusandhan National Research Foundation (ANRF) was launched by our Honorable Prime Minister, Shri Narendra Modi on 3rd November 2025. The main highlights were as follows:*

- *A ₹1 lakh crore initiative aimed at boosting private-sector-led R&D and innovation across sectors such as AI, biotech, clean energy, and semiconductors.*
- *Intended to strengthen domestic capabilities and reduce import dependence.*

***Roundtable conference with CEOs of Pharmaceutical sector on Regulatory Data Protection***

*Dr. Viranchi Shah mentioned that a meeting was convened by the Hon'ble Minister Shri Piyush Goyal to discuss issues relating to Data Protection and Data Exclusivity. The Government's broader objective was to facilitate innovation-led investments in India, particularly from certain European Union countries, which had sought clarity on regulatory data protection and exclusivity for innovations developed in India.*

*Dr. Shah stated that countries such as the US and several European nations follow TRIPS-plus compliance, offering extended periods of data exclusivity and protection to innovators. However, he emphasised that India's pharmaceutical industry is predominantly generics-driven and any introduction of data protection or exclusivity could hamper India's ability to serve domestic and global markets, delay product introductions, and adversely impact the overall growth of the industry. Dr. Viranchi Shah mentioned that he attended the meeting along with Dr. Veeramani and Mr. Madan and acknowledged the support received from the IDMA Secretariat, the National President and Dr. Gopakumar Nair in articulating the industry's position. IDMA made a clear representation that data protection or exclusivity should be avoided in the interest of public health and socio-economic considerations, particularly with respect to affordable availability of medicines. He further stated that, if data protection were to be considered unavoidable, IDMA suggested that it should be strictly limited to New Chemical Entities (NCEs) only, confined to basic innovations, with no extension to salts, esters, formulations, combinations or incremental innovations. IDMA also proposed that such protection should apply only to products that are patentable in India, in line with Section 3 of the Indian Patents Act and be limited to a period of six years from the date of first global approval, subject to the condition that the product is launched in India or approval is applied for in India within one year. Dr. Viranchi Shah mentioned that the collective efforts of IDMA have yielded constructive outcomes on this important issue.*

***World Pharmacist Day 2025***

*Dr. Vishwanath Karad MIT World Peace University and the School of Health Sciences & Technology, Pune celebrated the World Pharmacist Day on 25th September 2025 by organizing a one-day conference on "Think Health, Think Pharmacist". Mr. Daara B Patel was the Chief Guest at the Conference and delivered his address on the inspiring theme.*

*A comprehensive report outlining the Association's activities over the past year is provided in the following pages of this Annual Report.*

*We thank our National President, Mr. Bharat N Shah, Immediate Past National President and National Spokesperson of IDMA, Dr. Viranchi Shah, Honorary General Secretary, Ms. Aditi Kare Panandikar, our Immediate Past National President, Mr. Mahesh Doshi, along with all office bearers, Past Presidents, Committees Chairpersons, and Subject Matter Experts along with all the*

*Vice Presidents for their unwavering support and invaluable guidance. We also thank Dr. George Patani, Sr. Vice President and Mr. Mehul Shah, Vice President (Western Region) for their support and guidance at all times.*

*In reaffirming its steadfast commitment to the Indian pharmaceutical industry, IDMA has achieved significant progress during the year by expanding its membership base, strengthening its representation on influential policy-making platforms and amplifying its voice. The Association's proactive, future-focused interventions and representations stand as a testament to its enduring legacy and its growing stature as a leading advocate for the Indian pharmaceutical industry.*

*I would like to extend my heartfelt thanks to all EC members as well as every member of IDMA for their unwavering support, without which our Association would not have achieved the success it enjoys today. Thank you for your continued commitment, and we look forward to receiving your support in the years ahead.*

*I greatly appreciate the unstinted support of all the staff members at the Secretariat at Mumbai as well as Delhi Office.*

*Wishing you all a safe, healthy, fruitful and prosperous year 2026. Let us continue to collaborate, innovate and lead together as we STRIDE forward on this remarkable journey of VRIDDHI and Excellence, aligned with our 2026 theme -* ***"Innovating Today for a Healthier Tomorrow."***

*Yours Sincerely,*

***Daara B Patel***
*Secretary-General*

## REPORT OF BIOTECH COMMITTEE

This is a new committee and was formed during the 63rd Annual Day Celebrations held on 8th February 2025 at Mumbai.

**First Meeting of the IDMA Biotech Committee: (Hybrid Mode)**

Dr. Jaby Jacob was nominated as the Chairman of the Biotech Committee. He announced that the Committee would be organizing a series of webinars focusing on biotechnology products, particularly biosimilars, along with discussions on their regulatory pathways.

The Committee discussed the PRIP Scheme, highlighting the multiple opportunities available to leverage biotechnology funding. It was noted that the Department of Pharmaceuticals (DoP) and the Biotechnology Industry Research Assistance Council (BIRAC) have substantial funds, and the Committee plans to create awareness among IDMA members regarding these opportunities. The Committee also deliberated on the Biological Diversity Act, wherein members highlighted specific challenges faced by companies in the biotechnology sector. Concerns were raised regarding the broad scope of the Act—covering plants, animals, and microbes—which has led to practical difficulties in its implementation. The Committee acknowledged that this issue requires further detailed examination.

Ms. Aditi Panandikar emphasized the need to compile data on IDMA members engaged in biotechnology-related businesses and to identify key stakeholders so that they can be included in relevant discussions going forward.

This initiative marks a strong beginning to the Biotech Committee's efforts in knowledge dissemination and enhanced member engagement.

**IDMA Webinar on "Reimagining Indian Pharma: Biotechnology-Driven Drug Development in the Age of Innovation and Access" 5th December 2025**

The IDMA Biotech Committee successfully conducted its first webinar on 5 December 2025 from 11:00 a.m. to 12:30 p.m. Dr. Jaby Jacob, Chairman emphasized the significance of biotechnology and set the context for the session.

This was followed by an informative and excellent presentation by Dr. Ratneesh Jain, Principal Investigator, Nanomedicine Research Group, ICT Mumbai, and Founder of WeTranslate and Mumbai Biocluster.

The webinar was attended by approximately 40 participants, including senior members of the IDMA Executive Committee and received positive appreciation from all participants. The excellent presentation was published in IDMA Bulletin for the benefit of the readers.

## REPORT OF BULK DRUGS COMMITTEE

### Minimum Import Price (MIP) for products under the Production Linked Incentive (PLI) scheme

IDMA submitted a written representation to the Department of Pharmaceuticals on 13 January 2025 opposing the proposed imposition of MIP on ATS-8. The Association urged the Department to reconsider and withdraw the proposal, highlighting its adverse implications for domestic manufacturers and downstream users.

### IDMA Representation on Minimum Import Price (MIP) Proposal for ATS-8 (Intermediate of Atorvastatin API)

Members of the IDMA Bulk Drug Committee noted that the proposed MIP on ATS-8, though currently affecting a limited number of products, could set an undesirable precedent. It was emphasized that positioning MIP as a corrective measure for the PLI scheme is misplaced and risks distorting market dynamics, increasing costs, and adversely impacts domestic manufacturing.

### Meeting with Mr. Aditya Narain Singh, Scientist F, MoEF: 09.01.2025, Single Category

The meeting with Mr. Aditya Narain Singh, Scientist F, Ministry of Environment, Forest and Climate Change (MoEF), on 9th January 2025 was to discuss the issue related to the proposed *Single Category classification for Active Pharmaceutical Ingredients (APIs) and intermediates under the Environment Clearance (EC) framework*. IDMA mentioned that the matter is presently pending as the concerned official responsible for the issue is currently abroad. Mr. Singh advised that the issue be followed up after 20th January 2025 upon the official's return.

### Meeting regarding use of domestic petroleum industry products and by-products to manufacture precursors for the pharmaceutical industry

The Department of Pharmaceuticals (DoP) convened a hybrid meeting on 25th March 2025 to discuss the *Chemical Value Chain in the pharmaceutical sector*. The meeting was co-chaired by Mr. Amit Agrawal, Secretary, DoP, and Mr. Pankaj Jain, Secretary, Ministry of Petroleum and Natural Gas. Dr. Himanshu Roy, Director, DoP, presented an overview of the status, challenges and opportunities in strengthening the chemical value chain. IDMA highlighted key issues including user demand and tariffs, the need for incentives for domestic procurement, China's competitive advantage, PLI and other policy measures and the price gap in APIs and Intermediates. It was noted that certain products continue to be fully imported despite their manufacturability in India. While the sector remains at an early stage, growing interest in enhancing domestic production capabilities was observed.

## Indo-Pacific Economic Framework for Prosperity (IPEF)

**First meeting** of Technical Committee constituted to support in preparation of Action Plan under the Action Plan Team on Healthcare/Pharmaceuticals under Indo-Pacific Economic Framework for Prosperity (IPEF) Agreement.

The Department of Pharmaceuticals (DoP), vide its Order dated 19th December 2024, constituted a Technical Committee to support the preparation of an Action Plan under the Healthcare/ Pharmaceuticals Action Plan Team of the Indo-Pacific Economic Framework for Prosperity (IPEF) Agreement.

The inaugural meeting of the Technical Committee was held on 7th January 2025 under the chairpersonship of Ms. Gayatri Nair, Joint Secretary & Economic Advisor, DoP. Ms. Gayatri Nair provided an overview of IPEF, highlighting its four key pillars: Trade, Supply Chain, Clean Economy and Fair Economy. The IPEF includes 14 nations: the USA, India, Australia, Japan, South Korea, New Zealand and eight ASEAN members (Brunei, Indonesia, Malaysia, the Philippines, Singapore, Thailand, Vietnam, and Fiji).

India has opted out of the Trade pillar due to concerns over binding commitments but remains actively engaged in the other three pillars. Ms. Gayatri Nair sought suggestions regarding the creation of a resilient supply chain among the member nations.

## Second Meeting

The Department of Pharmaceuticals (DoP) organized the second meeting of the Technical Committee to support the preparation of the Action Plan under the Indo-Pacific Economic Framework for Prosperity (IPEF) Agreement on 21st February 2025 in virtual mode. The meeting was chaired by Mr. Amit Agrawal, Secretary, DoP, and was supported by Ms. Gayatri Nair, Joint Secretary and Economic Adviser, DoP.

The purpose of the meeting was to discuss the Indo-Pacific Economic Framework (IPEF) and focus was on enhancing supply chain resilience and reducing dependence on single-country sources. Mr. Yogin Majmudar represented IDMA in both meetings.

## Indo-Pacific Economic Framework Draft Work Plan

The Department of Pharmaceuticals (DoP) held a virtual meeting on the draft work plan for the Indo-Pacific Economic Framework, which was chaired by Ms. Gayatri Nair, Joint Secretary & Economic Advisor. During the meeting, key issues were discussed, including the need to focus on active pharmaceutical ingredients (APIs), key starting materials (KSMs), and essential raw materials. Mr. Yogin Majmudar raised concern regarding regulatory delays in market access and product registration, with a strong emphasis on the need for regulatory harmonization among

member countries. The Department of Pharmaceuticals also presented a list of critical raw materials, prepared based on current import dependencies.

**Meeting with Dr. Amandeep Garg, Addl. Secretary, MoEF**

Subsequent to meeting with Mr. Aditya Narain Singh meeting with Dr. Amandeep Garg, Addl. Secretary, MoEF was held when Office Memorandum dated 28th January 2021 concerning the issuance of Environmental Clearance (EC) for APIs and intermediates as a Single Category was discussed. Mr. Ved Prakash Mishra, Joint Secretary and Mr. Aditya Narain Singh, Scientist F, MoEF were also present. The matter was discussed in detail and IDMA was advised to submit a fresh, comprehensive representation, which was submitted on 11th April 2025 to Dr. Amandeep Garg, Additional Secretary, Ministry of Environment & Forest.

Mr. Yogin Majumdar recalled that in the 2020 meeting with the Secretary, it was agreed that regulatory focus should be on pollution load rather than internal plant operations. Accordingly, no fresh EC should be required for changes within the API / Intermediate category and companies may modify products, machinery or production levels provided there is no increase in effluent or pollution load. However, inconsistent implementation at the state level persists despite clear minutes, possibly due to lack of awareness or vested interests. He said that such delays of about 2 to 6 months are detrimental, especially in view of China Plus One opportunities requiring rapid product changes. BDMA has been informed and it was suggested that a fresh advisory be issued to states and that IDMA representation be ensured during follow-up meetings with the Secretary to expedite resolution.

**First Meeting of the IDMA Bulk Drug Committee**

The first meeting of the Bulk Drug Committee was held on 26th March 2025. Mr. Yogin Majmudar, Chairperson of the Bulk Drug Committee of IDMA welcomed his two Vice Chairpersons – Mr. Bipin Shah of Anuh Pharma & Ms. Neha Thakore of Avik Pharmaceutical and all the other members. He mentioned the need to create a comprehensive database of IDMA members engaged in API manufacturing and also in both APIs and formulations. In coordination with IDMA Secretary-General, Mr. Daara Patel, efforts have been initiated to reach out to members and compile this data to enable focused handling of API-specific issues and ensure accurate communication. The committee also discussed the need for reliable data on API manufacturers across India, noting inconsistencies in existing figures. It was decided to approach the State Drug Control Authorities, particularly in key pharmaceutical hubs, to obtain details of drug licenses issued for APIs and formulations to establish accurate numbers.

He mentioned that it was necessary to have a data-driven assessment of the PLI Scheme to know its impact. Plans were discussed to analyze import and export trends of KSMs and APIs covered under the scheme, before and after its implementation. Concerns were also raised about certain manufacturers exporting products instead of supplying the domestic market, thereby continuing dependence on imports.

He mentioned the discussions with the Department of Pharmaceuticals on flow chemistry and Corning Glass. The committee proposed inviting experts to deliberate on flow chemistry technologies at a forthcoming IDMA event. Mr. Yogin Majmudar also urged IDMA members, especially API manufacturers, to actively share feedback and issues for the Association to take up, stressing the importance of wider member engagement.

Meeting with regards to opinions on the Selection of Items for the IPEF Crisis Response Network (CRN) Tabletop Exercise (First Half of the Year).

Mr. Yogin Majmudar briefed the members on the virtual meeting held on 23rd April 2025, which was chaired by Ms. Gayatri Nair, Economic Advisor, Department of Pharmaceuticals (DoP). Mr. Majmudar shared IDMA's views on the proposed selection of pharmaceutical items for the upcoming *IPEF Crisis Response Network (CRN) Tabletop Exercise*. He highlighted that the proposed items Cephalosporin antibiotics and Acetaminophen (Paracetamol) are of strategic importance. He said that a significant portion of API requirements, including Cephalosporins and their intermediates, continues to be heavily dependent on imports from China. In the case of Paracetamol and its key intermediate Para Amino Phenol (PAP), he observed that while both are manufactured domestically, substantial imports continue, indicating a mixed sourcing pattern.

Mr. Majmudar further informed that IDMA is undertaking a detailed analysis of API import trends and domestic manufacturing, comparing pre and post PLI scheme periods to assess the PLI scheme's impact on reducing import dependence and strengthening indigenous production.

**Roundtable on API Supply Chain Resilience at US consulate**

The U.S. Consul General in Mumbai invited IDMA to participate in a high-level roundtable discussion on Supply Chain Resilience for Active Pharmaceutical Ingredients (APIs) for Essential Medicines on 5th June 2025. The roundtable was chaired by Dr. Jared Mondshein from the Critical and Emerging Technology Office, Washington, D.C., who is leading efforts under the U.S. - India TRUST (Transforming the Relationship Utilizing Strategic Technology) initiative.

Mr. Devesh Malladi mentioned that IDMA has a bigger group of MSMEs and that our members require financial support to set up plants in USA. The other suggestion was that we keep stock material against their confirmed orders and keep on supplying them as and when they want them. A brief record note was prepared and circulated to the participants. The Consulate forwarded IDMA a list of nine molecules which are required from India and the same was circulated to our members.

The list of nine molecules (APIs) are:

1. Acyclovir
2. Ampicillin

3. Epinephrine
4. Methylprednisolone
5. Vancomycin
6. Penicillin G
7. Clindamycin
8. Dexamethasone
9. Rifampicin

Mr. Yogin Majmudar said that the delegation acknowledged the differences between China and India, which created an opportunity to present India as a more reliable partner. He mentioned that he had the chance to emphasize this point, noting that one of the key reasons is the growing concern in the U.S. over supply chain dependence on China. With the current geopolitical narrative, there is apprehension that China could abruptly halt the supply of critical APIs. He gave the example that around 82% of amoxicillin used in the U.S. is currently imported from China.

This meeting gave an excellent opportunity to offer an alternate perspective and position India as a dependable source. Mr. Yogin Majmudar further pointed out that the U.S. should not attempt to revert to domestic API manufacturing, which had been phased out due to environmental, labour cost and regulatory challenges. He said that instead, a practical and strategic solution for India would be to manufacture key intermediates (N-1 and N-2 stages), thereby giving the U.S. better control over the final product quality without needing to rebuild a full API manufacturing base. He said that this suggestion was appreciated by the US delegates and is likely to be discussed further at internal levels in the U.S. administration. Mr. Yogin Majmudar added that this development represents a positive opportunity for Indian manufacturers. He also said that U.S. FDA approval may not be required for intermediate stages, allowing India to supply these without needing full API-level regulatory clearance, which simplifies the engagement process and opens new doors for Indian companies.

Mr. Ajit Singh informed that his company ACG is currently in the process of establishing a large facility in USA. He offered to support fellow industry members who were interested in setting up manufacturing units in the U.S., by sharing all relevant information such as cost details, site visit experiences across various States. He said that based on their experience, overall costs in the U.S. are surprisingly lower than in India, with the only major exception being labour costs. To address this, his company is actively working to automate as many processes as possible, thereby minimizing the impact of higher manpower expenses. He added that capsule manufacturing which is more labour-intensive than API production may face different challenges.

Mr. Ajit Singh mentioned that U.S. States are actively competing for investments and are eager to attract companies that create jobs, and if a company commits to employing at least 100 people, many State Governments are willing to offer generous incentives, including VIP-level support. In

his case, State representatives even arranged private air travel for his team to visit and assess different locations

**Meeting of the Bulk Drugs Committee 28th May at 3:00 PM at the IDMA Office**

Mr. Yogin Majmudar discussed in the committee meeting the key long-term strategies to strengthen India's API industry. These included simplification of R&D and audit processes, addressing issues related to the Biodiversity Act, streamlining the environmental clearance mechanism, and supporting MSMEs through reduction in import duties and easing of regulatory requirements.

The committee also deliberated on increasing challenges in sourcing APIs and chemicals from China. It was suggested that the Government take faster action on anti-dumping measures, consider blanket duties based on metric tonnage to safeguard domestic manufacturers, and introduce incentives to encourage domestic sourcing. Mr. Majmudar emphasized that all such measures must remain compliant with India's WTO obligations. Concerns were also raised regarding delays in approvals at both State and Central levels.

Mr. Yogin Majmudar further informed that IDMA has planned several strategic initiatives to strengthen the API sector, including organizing visits to 2–3 NIPER institutions engaged in API R&D to explore collaboration opportunities. It was also decided to reach out to Ms. Aparna (former DoP official) for guidance and Government support. Additionally, IDMA will compile data on existing collaborations between Indian and European biotech companies.

**Stakeholder Consultation on Maharashtra's Active Pharmaceutical Ingredients (API) Policy**

The Government of Maharashtra is in the process of formulating a comprehensive Active Pharmaceutical Ingredients (API) Policy with the objective of strengthening the pharmaceutical manufacturing ecosystem, promoting self-reliance and enhancing the State's contribution to India's healthcare needs and export potential. The meeting was chaired by Dr. Rajendra Bharud, IAS, Additional Development Commissioner (Industries), Government of Maharashtra. IDMA submitted its suggestions and recommendations through a formal letter addressed to the Hon'ble Minister of Industries, Mr. Uday Samant.

**Meeting with Ernst and Young on Maharashtra's Active Pharmaceutical Ingredients (API) Policy at IDMA office (Hybrid)**

The Government of Maharashtra has engaged Ernst & Young (E&Y) to assist in formulating the State's Active Pharmaceutical Ingredients (API) Policy and in this regard, Ms. Surbhi Sharma from E&Y had a meeting with IDMA members at the IDMA office on 06th June 2025. IDMA shared comprehensive inputs including policy suggestions, benchmarking data, inter-state comparisons, the best global practices, and other relevant information to support the development of a robust API policy for Maharashtra. Dr. Chinmay Majmudar prepared a detailed industry representation

outlining key recommendations for the proposed API policy and was formally shared with Ms. Surbhi Sharma during the meeting.

**Draft Notification G.S.R. 365(E) dated 3rd June 2025 under Plastic Waste Management Rule 2016**

Mr. Yogin Majmudar discussed the implications of Draft Notification G.S.R. 365(E) dated 3 June 2025 issued under the Plastic Waste Management Rules, 2016, on the Pharmaceutical industry.

IDMA would be submitting a representation seeking exemption of pharmaceutical products from the mandate on the use of recycled plastic packaging under the said draft Notification. He emphasized that the use or reuse of recycled plastic in pharmaceutical packaging is prohibited under existing laws and guidelines due to the risk of contamination, toxicity and potential adverse impact on drug efficacy, stability and patient safety. Mr. Yogin Majmudar further stated that Schedule M of the Drugs & Cosmetics Rules mandates strict compliance with pharmacopeial standards for packaging materials and expressly prohibits the use of second-hand materials. Accordingly, he stressed the need for IDMA to represent the industry's position to the concerned Ministry and seek a complete exemption for pharmaceutical products in the final Notification, in the interest of regulatory compliance and public health.

**Meeting with Mr. Rhys Dubin, U.S. Department of State U.S. – India TRUST Initiative: API Supply Chain Resilience**

Mr. Bharat Shah informed that a meeting was held with Mr. Rhys Dubin from the U.S.–India TRUST (Transforming the Relationship Utilizing Strategic Technology) Initiative on 09.09.2025 to explore collaboration opportunities for strengthening API supply chain resilience between India and the United States. Mr. Dubin highlighted that the U.S. has identified 26 critical APIs, including 9 priority APIs and referred to earlier TRUST roundtable discussions held in Washington D.C. and New Delhi.

Dr. Dhaval Vashi from Atul Pharma presented Atul Pharma's fully backward-integrated Acyclovir manufacturing capability, demonstrating India's readiness to supply the U.S. market, subject to customer commitment, financial support and long-term procurement assurance.

Ms. Aditi Kare Panandikar further explained the TRUST Initiative, outlining the 9 priority APIs (4 fermentation-based and 5 chemical-based), concerns related to dependence on China and industry expectations from the collaboration. She added that Mr. Dubin emphasized the U.S. focus on stockpiling, supply oversight and engagement with Indian companies and academia and proposed a pilot project covering two APIs one fermentation-based and one chemical-based with participation from 5–10 Indian companies, involving technology transfer and assured procurement under the TRUST framework.

**Meeting of Stakeholders to Discuss the MIP (Minimum Import Price) for Potassium Clavulanate and its Intermediate 21.08.2025**

A stakeholders' meeting on the proposed Minimum Import Price (MIP) for Potassium Clavulanate and its intermediate was held on 21st August 2025 under the chairmanship of Shri Awadhesh Chaudhary, Senior Economic Advisor and Additional Secretary, Department of Pharmaceuticals. Dr. Himanshu Roy made the presentation.

During the discussions, Mr. Yogin Mazumdar highlighted that earlier import control measures were quantity-based, whereas the current proposal is value-based. While reaffirming its support for policy measures to strengthen domestic API manufacturing, he expressed clear reservations regarding the MIP mechanism. It was noted that restricting imports through an MIP may result in unintended outcomes, including the risk of added price advantages accruing to foreign suppliers rather than supporting the domestic industry.

IDMA recommended that alternative trade remedies such as anti-dumping duties and safeguard duties be considered, as these more effectively address injury to the domestic API sector. Where price-based measures are considered unavoidable, IDMA suggested that the differential be collected as a cess, which could be reinvested into research and development, capacity building, and technology upgradation for the API industry.

IDMA also emphasized that MIP, if used at all, should be approached with caution and only as a short-term measure.

**Submission of Notes on API & Intermediates Category and Production Enhancement Without Pollution Load Increase**

Mr. Yogin Majmudar informed the members that he recently held a detailed discussion with the concerned officer to seek further clarity on IDMA's earlier submission regarding the issuance of Environmental Clearance (EC) and Consent to Operate (CTO) under a single category of "APIs and Intermediates." Based on the feedback received, two concise notes were prepared and submitted on 27 October 2025 for consideration:

Note 1: Addresses implementation gaps in the Office Memorandum dated 28th September 2021 (F. No. 22-23/2019-IA.III) and proposes a pragmatic approach involving prior intimation and deemed approval to enable timely operationalization of the single-category approval mechanism.

Note 2: Highlights the limited implementation of Gazette Notification S.O. 980(E) dated 2 March 2021, particularly with respect to permitting increased production without additional pollution load. It also recommends incentivising environmental performance improvements, including adoption of Zero Liquid Discharge (ZLD) systems, solvent recovery, and energy-efficient technologies.

Mr. Majmudar stated that these suggestions are intended to address existing implementation bottlenecks while promoting ease of doing responsible business in the API sector, striking a balance between environmental safeguards and industrial competitiveness.

**Nominating Experts for identifying Critical Bulk Drugs which may be supported for production in the country**

The Department of Pharmaceuticals (DoP) has constituted a committee on 06th October 2025 to identify critical bulk drugs for potential support under domestic production initiatives. Mr. Mahesh Doshi has been nominated to represent IDMA on this Committee. The first meeting was held on 16th October 2025, which was a brief preliminary discussion of about ten minutes. Mr. Mahesh Doshi stated that Mr. Madan attended the meeting on his behalf, and the Committee has sought industry feedback to identify critical bulk drugs. Once the list of such drugs and industry responses are finalized, he will update the Association and other members accordingly.

**Information wrt Iso-Propyl Alcohol as sought by DoP**

Ms. Neha Thakore informed the members that India is steadily scaling up domestic production to meet national requirements with demand driven not only by the pharmaceutical sector but also emerging industries such as semiconductor and chip manufacturing. India currently produces about half of its total requirement, though domestic capacity is expected to meet the full national demand within the next three years. IDMA had earlier responded to the Joint Secretary, DoP on 11 November 2025, providing detailed inputs on IPA consumption and supply dynamics. India consumes approximately 170,000 MT of IPA annually 70–75% of national demand with only 15% used as IP grade. Major domestic producers such as Deepak Fertilizers, Deepak Nitrite and the upcoming IOCL capacity supply IP-grade material and overall capacity is increasing. Despite this, India still imports nearly 100,000 MT, largely from China.

Ms. Neha Thakore highlighted that IPA contributes less than 5% to the final cost of pharmaceutical formulations; however, the sharp decline in Chinese prices by nearly 20–30% is adversely impacting domestic manufacturers as Chinese suppliers are selling at or below cost while continuing to expand capacity.

## REPORT OF EMPLOYEES RELATION & DEVELOPMENT COMMITTEE

Mr. Atul Parab, Chairman of the Employees Relation and Development Committee of IDMA and Associate Vice President & Head Sales HR, (India Branded Business) – Alkem Laboratories thanked the National President for his nomination and announced that Mr. Vijay Dalvi of Blue Cross Laboratories and Mr. Chinmaya Mohanty of RPG Life Sciences / Wallace Pharmaceuticals would be joining the Advocacy Group as Co-Chairmen for this two-year term 2025 – 2026.

**IDMA wins the High Court Case vide Order dated 4th February 2025 passed by the Hon'ble High Court of Karnataka, Bangalore with regards to the Writ Petition No 12194 - 12209 /2014 between IDMA & 10 others vs Government of Karnataka**

Mr. Atul Parab stated that on reading of Section 13(1)(a) of the Factories Act, 1948, the Hon'ble Judge observed that while the appropriate Government is empowered to fix the number of hours constituting a normal working day (inclusive of specified intervals), it does not have the authority to fix the commencement or ending of working hours. A complete reading of the provision clearly establishes that the State Government's power is limited to fixing normal working hours and does not extend to prescribing the start or end time of work.

Mr. Parab mentioned that this issue also came up for consideration before the Patna High Court in M/S. INDIAN DRUG MANUFACTURERS ASSOCIATION vs THE GOVERNMENT OF BIHAR in Civil Writ Jurisdiction Case No.9237/2017. The Division Bench of the Patna High Court has taken a view that the Government has no power to fix the commencement of the working hours and ending of working hours. It is also clear from the reading of Section 13(1)(a) of the Act, 1948.

Under these circumstances, this Court is of the view that the petitioner is justified in contending that the Notification is without jurisdiction. The petition challenged the Notification dated 27.07.2013 issued by the Labour Commissioner's office which sought to fix working hours for Medical Representatives. After thorough deliberation, the Hon'ble Court has quashed the notification on merits, thereby upholding our stand on this critical matter.

IDMA appreciated the efforts of the entire IDMA team led by Mr Daara Patel and the Advocacy group led by Mr. Atul Parab, Mr. Vijay Dalvi, Mr. Chinmaya Mohanty along with the earlier members like Mr. Ramesh Balgi, Mr. Jayesh Shah, Mr. C I Shetty, Mr. Shivaji Kanade, Mr. Saidutta, Mr. Santoush Kadam and other stalwart leaders of the pharmaceutical sector for their unwavering support and relentless efforts in championing our cause.

Mr. Atul Parab mentioned that this was a significant and successful judgment achieved after more than ten years of sustained effort. He expressed his sincere gratitude to all Committee Members and the concerned pharmaceutical companies for their continued support in pursuing this important cause on behalf of IDMA.

**IDMA Representation on 27th May 2025 to Dr. Pramod P Sawant, Hon'ble Chief Minister of Goa, Government of Goa : Request for Extension of Essential Services Maintenance Act (ESMA) Orders beyond 10 June 2025**

IDMA made a Representation to Dr. Pramod P Sawant, Hon'ble Chief Minister of Goa on 27th May 2025. IDMA sincerely thanked the Government of Goa for implementing and extending the Essential Services Maintenance Act (ESMA) to preserve public order and safeguard essential services until 9 June 2025 and further thanked the Government of Goa for declaring the

manufacturing, packaging, distribution and transportation of pharmaceutical products and their components as essential services under ESMA along with the extension order issued in 2024. These orders have played a vital role in enabling member companies to expand operations and product lines, generate employment and ensure uninterrupted supply of essential medicines to both domestic and global markets.

In view of the above, IDMA respectfully urge the Government of Goa to extend the ESMA orders beyond 9 June 2025 for a further period of six months, so as to ensure uninterrupted essential services, safeguard employee safety, maintain industrial harmony and uphold Goa's position as a global pharmaceutical hub.

IDMA Representation was successful and the Government of Goa has invoked the Goa Essential Services Maintenance Act, 1988 (ESMA), stating that the ESMA Order shall remain in force for a further period of six months with effect from December 17, 2025.

**IDMA Representation for withdrawal / modification of office Order dated 28.05.2025 restricting entry of Medical Representatives in Central Government Hospitals**

IDMA submitted a Representation to the Directorate General of Health Services, New Delhi on 12th June 2025 and respectfully expressed our concerns regarding the recent Government Order issued on 28th May 2025 which restricts the entry of Medical Representatives (MRs) into Central Government Hospitals. This directive, at first glance, disrupts a crucial channel of communication between the pharmaceutical industry and healthcare professionals, and may carry unintended consequences for public health, medical innovation and patient care. The dissemination of vital scientific and clinical information that supports the medical community.

The major points explained and elaborated were the following:

(1) The Value of the MR–Physician Interaction

(2) International Best Practices

(3) Possible Implications of a Blanket Ban

India has taken proactive steps through the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) for a robust, self-regulatory framework adhered to by IDMA member companies. This ensures ethical promotion and responsible engagement with healthcare professionals. In view of the above, we most respectfully requested the Ministry to:

i. Suitably modify the office order dated 28.05.2025 and/or

ii. Permit regulated and time bound access to Medical Representatives with restrictions. This will facilitate scientific exchange with Healthcare professionals.

**Webinar on Employment Linked Incentive (ELI) Scheme with Pharma & Medical Devices Association Members on 14.07.2025**

Mr. Vijay Dalvi attended the webinar organized by the Department of Pharmaceuticals with representatives of Associations from the Pharmaceutical and Medical Devices sectors to discuss the Employment Linked Incentive (ELI) Scheme. Mr. Dalvi mentioned that there were fruitful deliberations during the webinar.

**Judgement Copy CWJC No. 9237 of 2017 (Indian Drug Manufacturers' Association and Others vs. The State of Bihar and Others) – before Hon'ble Patna High Court**

IDMA recently obtained a significant High Court order from Patna regarding the regulation passed by the Bihar Commission of Labour. This order pertains to the working hours of Medical Representatives, specifically fixing the duration at 8 hours, inclusive of a lunch break and restricting working hours until 5 pm. The High Court has directed the Government to refrain from implementing this notification for Medical Representatives, taking into consideration the flexibility required in their working hours and the availability of Doctors. IDMA appreciated the member companies for their active participation in this matter and thanked the Advocacy Group Members - Mr. C I Shetty from Alembic, Mr. Jayesh Shah from Sun Pharma, Mr. Ramesh Balgi from USV and Mr. Atul Parab from Alkem Laboratories for their unstinted support towards this case. IDMA mentioned that their dedicated and diligent involvement had been instrumental in achieving this favorable judgment, which will greatly benefit all participating companies in their business processes.

**High Court of Jharkhand, Ranchi - WPC No. 1332/2019**

Mr. Atul Parab has filed a Writ Petition no. WPC No. 1332/2019 and the writ has been preferred before the Hon'ble High Court of Jharkhand at Ranchi on behalf of IDMA wherein it has prayed for the issuance of a writ of certiorari or any other appropriate writ, order or direction quashing the Notification bearing No. 2179 dated 13.09.2011 issued under the signature of the Joint Secretary, Labour Employment and Training Department, Government of Jharkhand, Ranchi fixing the work timings of Sales Promotion Employees (hereinafter referred to as SPE's) working in the State of Jharkhand since the said notification is *ultra vires* being contrary to the provisions of Section 12 of the Sales Promotion employees (conditions of service) Act, 1976 and Section 13(1)(a) of the Minimum Wages Act, 1948. Moreover, the said notification suffers from the vice of sub-delegation since it has been issued under an executive order and not a rule framed under the provisions of the Minimum Wages Act, 1948.

An I.A No. 1360/2026 has been preferred in this Writ Petition for stay of further implementation and operations of Notification No. 2179 dated 13.09.2011. The instant writ petition is running Actively on the board of The Hon'ble High Court of Jharkhand at Ranchi and is due to be heard on 03.02.2026.

## REPORT OF ESG COMMITTEE

**Meeting of ESG Committee on 20th February 2025**

Ms. Neha Thakore, Chairperson, presided over the first meeting of the IDMA ESG Committee held on 20th February 2025. She announced that Ms. Mansi Kampani from Encube Ethicals would be the Vice Chairperson of the Committee and reaffirmed that IDMA is firmly committed to the principle of 'Safety for All' in alignment with the National Vision of *Viksit Bharat*. To advance this objective across the pharmaceutical sector, IDMA proposes to undertake a series of initiatives during the year, including targeted awareness campaigns, capacity-building workshops and sustained engagement with industry stakeholders. Highlighting the industry's commitment to POSH (Prevention of Sexual Harassment), Ms. Thakore mentioned that what began as an internal IDMA initiative approximately two years ago has now been formally institutionalized in 2025. This formalization underscores IDMA's intent to strengthen industry-wide safety, regulatory compliance and workplace conduct standards. She further emphasized that POSH, within the broader ESG (Environmental, Social, and Governance) framework is a critical component of the 'Social' pillar.

Ms. Neha Thakore mentioned that during the National Safety Week observed by the National Safety Commission, IDMA supported the initiative by posting content on creating safe workplaces on LinkedIn and requested members to amplify the message through reposts. She encouraged all members active on LinkedIn to follow the IDMA page and actively support the dissemination of such initiatives to enhance outreach and impact.

Ms. Neha Thakore mentioned that POSH should not be viewed narrowly only in the context of sexual harassment, but rather as part of a broader inclusivity and dignity-at-work framework. She highlighted the importance of embracing diversity and mentioned that studies demonstrated that a diverse and inclusive workforce can result in productivity gains of up to six times, underscoring the business and social imperative for the industry to actively promote such practices.

**IDMA CARES - Creating Accountable, Respectful, Empowered & Safe Workplaces**

Mr. Bharat N Shah, National President along with Ms. Neha Thakore, Chairperson – ESG Committee historically launched the IDMA CARES program for IDMA & the Indian Pharmaceutical Industry. IDMA CARES stands for Creating Accountable, Respectful, Empowered & Safe Workplaces. Under the IDMA CARES umbrella, the first initiative titled "Did You Know?" had been launched. This initiative focused on sharing facts and insights related to mental and physical workplace safety. Ms. Neha Thakore informed the committee that IDMA will be working with Jet Synthesis, a professional agency specializing in POSH-related content creation and design. The campaign content will be disseminated through digital platforms such as LinkedIn and Twitter. The second initiative was titled "Didn't You Know?" and/or "Oh, I Didn't Know This!" aimed at generating greater engagement and reflection. Under this initiative, influential members from the

pharmaceutical industry would be invited to record short video reels reacting to workplace safety and inclusive facts. These videos would be shared on IDMA's social media platforms.

**IDMA CARES 2025 Launch Event - An Initiative by ESG Committee & Next Gen Committee on 18th July 2025**

IDMA created history with the launch of IDMA CARES – Creating Accountable, Respectful, Empowered & Safe Workplaces, a landmark industry initiative aimed at strengthening workplace culture across the Indian pharmaceutical sector. The initiative was formally launched on Friday, 18th July 2025, in Mumbai at the auspicious hands of Mr. Bharat N. Shah, National President, IDMA and Mrs. Vijaya Rahatkar, Chairperson, National Commission for Women (NCW).

IDMA CARES event was championed by IDMA's ESG Committee and Next Gen Committee and marked a significant step forward in the Association's continued efforts to promote responsible business practices and people-centric growth. The launch event witnessed the participation of over 200 senior leaders and future leaders from across the country, reflecting the pharmaceutical industry's strong commitment to building inclusive, ethical, and future-ready workplaces. The initiative reinforces IDMA's vision of building a resilient and progressive pharmaceutical ecosystem that places equal emphasis on quality, compliance, and human values, while aligning with evolving global ESG expectations.

Ms. Neha Thakore set the tone for the event and expressed her sincere gratitude to Mr. Bharat Shah, National President, Mr. Mehul Shah, Dr. Viranchi Shah, Mr. Daara Patel, Dr. George Patani and the members of the Next Gen Committee and ESG Committee for their invaluable support in making the launch of IDMA CARES a grand success. Ms. Thakore emphasized that Environmental, Social and Governance (ESG) has become an increasingly important agenda for the pharmaceutical industry. She mentioned that the pharmaceutical sector is fundamentally about *"doing good and doing well"* simultaneously and that IDMA CARES has been designed to create awareness across the industry on the future of pharma, with a focus on softer skills, sustainability and ESG-driven growth. She further stated that ESG initiatives are rapidly emerging as key growth drivers, with multinational companies already prioritizing them and that the broader ecosystem is expected to align with these expectations in the near future.

The IDMA CARES event witnessed excellent participation and featured educational and inspiring video messages from Mrs. Kiran Mazumdar-Shaw, Executive Chairperson, Biocon Limited and Biocon Biologics Limited and Dr. Anup Yadav, IAS, Secretary, Women and Child Development, Government of Maharashtra. The programme also included a presentation titled 'Workplace Culture and Sexual Harassment Prevention through a Leadership Lens' delivered as a micro masterclass by Ms. Priyanka Chaturvedi Agrawal, Inclusional and Jet Social Impact Head, followed by an engaging panel discussion curated by PricewaterhouseCoopers (PwC). Together, these elements made the event a meaningful and impactful beginning to the IDMA CARES journey.

Dr. George Patani remarked that every past President of IDMA has contributed to strengthening the organization and that this collective enhancement is reflected in the phenomenal work being undertaken by the ESG and Next-Gen Committees.

**Above all, IDMA CARES served as a powerful reminder that IDMA and the pharmaceutical industry genuinely care.**

## REPORT OF EXCISE & TAXATION COMMITTEE

Mr. B G Barve, Chairperson, Excise & Taxation Committee of IDMA nominated Ms. Ketki Raj Wadhawa as Vice Chairperson for the year 2025 – 2026 at the first meeting of the Committee Chairpersons with the National President.

### Pre-Budget meeting for Union Budget 2025-2026

IDMA presented its Budget recommendations on 19th November 2024 during the Pre-Budget Meeting for Union Budget 2025-2026. IDMA was led by Ms. Ketki Wadhawa along with Mr. Sandeep Sharma and Mr. Madan. The four key issues discussed were:

- Allow amortization of upfront premium for leasehold land/premises over the lease period.
- Permit allowability of sales promotion expenses for pharmaceutical companies under Section 37(1).
- Address administrative challenges, such as Dividend Distribution Tax Credit.
- Increase the Section 80JJAA limit from ₹25,000 to ₹50,000.

Mr. B G Barve said that IDMA's key recommendations were reinstating the 200% weighted deduction for R&D expenditure under Section 35(2AB) to promote innovation and extend the benefits of Section 115BAB to further enhance industry competitiveness. He said that IDMA suggested removing the requirement for payers to issue TDS/TCS certificates and prescribing specific timelines for refund issuance and completion of appeals before CIT (Appeals). IDMA also recommended omitting Clause 44 from Tax Audit requirements related to GST expenditure breakup and excluding physician samples and product reminders from the purview of Section 194R.

Mr. B. G Barve said that in the scope of personal income tax, IDMA supports allowing NPS contributions under Section 80CCD(1B) as a deduction in the new tax regime, thereby encouraging retirement savings. He said that on customs, IDMA proposed revising the Basic Customs Duty (BCD) tariff rate for sub-heading 293359 to 7.5% to boost competitiveness and introducing an amnesty scheme to address and resolve past customs litigation effectively.

### Budget Review Meeting with KPMG

Mr. B. G. Barve informed the members that the Union Budget for the year 2024–2025 was

presented on February 1, 2025. As per IDMA's annual practice, IDMA in collaboration with KPMG, organized a Webinar on the Budget Review on February 4, 2025. The webinar provided valuable insights into the implications of the Union Budget 2025 for the pharmaceutical industry, including a detailed discussion on the Representations submitted by IDMA. The session was well received and highly informative. KPMG has consistently been a strong supporter of IDMA initiatives and the webinar featured three senior speakers from KPMG along with Mr. B. G. Barve, Ms. Ketki Wadhawa and members of their Committee who actively contributed to the deliberations.

**Meeting with KPMG : Discussion on New Income Tax Bill**

Mr. B.G. Barve informed the members that the KPMG team had a meeting at IDMA Office on 16th April 2025 to discuss the proposed New Income Tax Bill. During the discussions, several anomalies were identified, particularly those impacting scientific research and operational aspects of the pharmaceutical industry. He said that based on these observations, IDMA is in the process of drafting a formal Representation to the Finance Ministry & the concerned authorities with a request to reconsider and revise the provisions that may adversely impact the industry.

**IDMA Representation to align GST rate on API to prevent Inverted Duty Structure and Extension for Implementation of revised MRP**

IDMA has submitted a representation to the Government on the need to align the GST rate on Active Pharmaceutical Ingredients (APIs) with that of formulated medicines to prevent an inverted duty structure and to seek an extension for implementation of revised MRPs following the upcoming GST 2.0 reforms. Mr. B G Barve mentioned that the representation was prepared in response to the Hon'ble Prime Minister Shri Narendra Modi's announcement on 15th August 2025 regarding GST 2.0 which aims to simplify the tax structure and reduce GST rates, especially for essential and mass-use items. He said that under the proposed structure, the medicines formulated under Chapter 30 are expected to move from 12% to 5% GST, while APIs under Chapter 29 continue to attract 18% GST. This creates a significant inverted duty structure where input taxes exceed output taxes, leading to accumulated unutilized ITC, increased working capital burden and reduced competitiveness for Indian pharmaceutical manufacturers particularly the MSMEs and Exporters. IDMA recommended that the GST rate on APIs used in pharmaceutical formulations should be reduced from 18% to 5% in line with finished medicines to support domestic value addition, working capital efficiency and competitiveness under the Government's "Make in India" and "Atmanirbhar Bharat" vision.

Mr. B G Barve further mentioned that with the expected reduction of GST rates on medicines, there will be a need to revise MRPs across the supply chain. He said that in the representation IDMA has requested the following:

- The Government and NPPA issue clear guidelines and allow adequate time (minimum six months) for MRP transition to avoid product recalls and supply disruptions.

- Post-supply tax credit notes under Section 34 of the CGST Act be permitted to enable companies to pass on the benefits of GST reduction to distributors and retailers.
- NPPA and CDSCO issue necessary notifications and clarifications, similar to those during the 2017 GST rollout to enable smooth re-labelling and compliance.

Mr. Barve said that the inverted duty structure on APIs and providing a well-planned transition for MRP revisions are essential to ensure the success of GST 2.0 reforms, maintain affordability and secure uninterrupted availability of medicines to patients across the country. IDMA has circulated FAQs to members and published them in the IDMA Bulletin.

**IDMA Representation - To Extend the Time Limit for Payment under Section 15 of the MSME Development Act, 2006 and allow the deduction of section 43B(h) and corresponding 37(2)(g) of Income Tax Bill 2025 if paid before the due date of filing return**

IDMA submitted a representation to the Hon'ble Finance Minister, Mrs. Nirmala Sitharaman and Hon'ble Shri Jitan Ram Manjhi, Minister of Micro, Small and Medium Enterprises on 02nd September 2025, seeking rationalization of payment timelines and tax deduction provisions relating to transactions with Micro and Small Enterprises (MSEs). The representation requests (i) extension of the statutory payment period under Section 15 of the MSME Development Act, 2006 from 45 days to 90 days, and (ii) alignment of Section 43B(h) of the Income Tax Act (retained as Section 37(2)(g) in the Income Tax Bill, 2025) with other clauses of Section 43B by allowing deduction where payments to MSEs are made on or before the due date of filing the return of income.

IDMA highlighted that while the intent of these provisions to ensure timely payments and improve liquidity for MSEs—is commendable, the current framework creates significant operational and financial challenges, particularly for the pharmaceutical sector. Factors such as stringent quality control and regulatory testing timelines, export-driven credit cycles, increased compliance costs under revised Schedule M, working capital pressures, and global trade uncertainties make adherence to a 45-day payment limit impractical.

The representation emphasized that extending the payment window to 90 days and permitting deductions if payments are made before the return filing due date would balance the interests of MSEs with business realities, prevent unintended disincentives to sourcing from MSEs, and align with the Government's objectives of Ease of Doing Business, Make in India, Atmanirbhar Bharat, and export growth. IDMA also suggested constituting an industry–government working group to address sector-specific implementation challenges.

**Pre-Budget meeting for the Union Budget 2026-27**

The Pre-Budget Meeting for the Union Budget 2026–27 was held by the Department of Revenue, Ministry of Finance, on 17 November 2025 in New Delhi. The meeting was chaired by Mr. Vivek Chaturvedi, Member (TP & Legal), CBIC. IDMA made a thorough and impactful presentation at

the meeting. Ms. Ketki Wadhwa and Mr. Sandeep Sharma represented IDMA at the said meeting. They presented IDMA's views and deliberated in detail on the key issues and recommendations. One of the major issues highlighted was the GST refund eligibility on export proceeds subject to foreign withholding tax under Double Taxation Avoidance Agreements (DTAA).

Mr. B G Barve mentioned that both OPPI and IPA supported IDMA's recommendations for the Union Budget 2026-27.

**Received communication from the Rajya Sabha Secretariat along with letter No.LAFEAS-HF24/9/2025-H and FW-RSS, dated 19th December 2025**

In response to the Government's invitation for stakeholder inputs on the Union Budget proposals for FY 2026–27, IDMA submitted comprehensive suggestions covering health, pharmaceuticals, and medical research on 09th Jan 2026. The recommendations focused on strengthening India's innovation ecosystem, improving tax and GST structures, ensuring sustainability of price-controlled medicines, and promoting self-reliance in critical raw materials.

Key proposals included reinstatement of the 200% weighted tax deduction for in-house R&D under the Income Tax Bill, 2025, with an expanded definition of scientific research to cover regulatory approvals and clinical trials, to accelerate innovation and private sector investment. IDMA also highlighted the need to rationalize GST rates on APIs, KSMs, and intermediates to address the persistent inverted duty structure, reduce working capital blockage, and support MSMEs and exporters.

On pricing policy, IDMA suggested refinements to the DPCO framework through a balanced pricing methodology that factors in input cost volatility, compliance investments, and supply sustainability, along with faster regulatory pathways for complex formulations. The submission further emphasized promoting domestic API and raw material manufacturing through fiscal incentives and strengthening medical research and public health infrastructure via targeted funding, industry–academia collaboration, and support for emerging technologies such as AI and digital health.

## REPORT OF FINANCE & ADMINISTRATION COMMITTEE

**Upgradation of Tally Accounting Software**

Mr. Mehul Shah, Chairman – Finance Committee, informed that the process of upgrading the Accounting System at IDMA has been initiated. For this purpose, H K Doshi & Co., Chartered Accountants have been appointed to oversee the overall upgradation of the accounting systems, and Planet Accounting Solutions have been engaged for the upgradation of the Tally Accounting Software. Mr. Kirit Vora of Encube Ethicals is assisting IDMA in this upgradation process, which is being carried out in two phases.

**H K Doshi & Co., Chartered Accountants**

H K Doshi & Co., Chartered Accountants have been appointed from August 2025 to oversee the upgradation of the accounting systems with the objective of enabling preparation of Monthly MIS reports, Monthly Closing of books with appropriate provisions, creation of cost centres for event-wise accounting, rationalisation and clearing of unwanted account heads, among other improvements. The upgradation work is planned in two phases. Phase I has been successfully completed by H K Doshi & Co.

**Planet Accounting Solutions**

Planet Accounting Solutions are facilitating the upgradation of the Tally Software Systems, including preparation of e-Tax Invoices and Proforma Invoices and forwarding the same to multiple members through email directly from the Tally software in a Single Click. They are also developing systems for renewal of membership fees as well as subscriptions for IDMA Bulletin and Indian Drugs. This upgradation work is currently in progress and is expected to be fully functional from April 2026 onwards. The Tally system will be aligned with the new membership slabs and merged with turnover data, enabling preparation and dispatch of invoices at the click of a button. This process will result in significant time savings and with improved accuracy.

**Members' Annual Turnover Data**

Mr. Mehul Shah informed the Committee that IDMA has obtained the Annual Turnover Data of its members from a highly reliable source, viz. Private Circle (Bharatiasha Technologies Pvt. Ltd.). This data will facilitate the preparation of proforma invoices based on the actual turnover of members.

**Membership Fees – Proposal for Rationalization and Simplification**

Mr. Mehul Shah placed before the Executive Committee a proposal for the rationalization and simplification of the Membership Fee Structure, proposed to be implemented from the forthcoming financial year, with the objective of strengthening the financial health of the Association. He informed that several discussions have already been held with the Office Bearers, Executive Committee, and State Boards regarding the proposed fee structure. He expressed confidence that the proposal would be approved at the next Executive Committee Meeting and subsequently placed before the forthcoming Annual General Meeting for consideration and approval by way of a Resolution.

**Approval of Final Accounts for FY 2024-25**

Mr. Bharat Shah, National President, informed the members that, on behalf of Mr. Mehul Shah, Chairman – Finance Committee, he placed before the Executive Committee the audited accounts of the Association for the financial year 2024–2025. He mentioned that during the year, the Association recorded a total income of ₹4.55 crore against a total expenditure of ₹4.54 crore, resulting in a surplus of ₹34,500. During the year, two major events, namely the Annual

Day and the 23rd Pharmaceutical Analysts' Convention (PAC), were successfully organized. In addition, the Association conducted six major programmes in collaboration with the Department of Pharmaceuticals (DoP) and CDSCO on Revised Schedule M at Daman, Visakhapatnam, Baddi, Bengaluru, Ahmedabad and Kolkata. These programmes were conducted without charging any registration fees. While a few members extended financial support, it was noted that IDMA bore the majority of the expenses for these initiatives. The renewed and paid membership strength stood at 651, reflecting a marginal increase from 641 in the financial year 2023–24.

Mr. Bharat Shah, National President together with the Executive Committee Members placed on record their appreciation for the efforts and contributions of Mr. Mehul Shah in strengthening and enhancing IDMA by spearheading several new and successful initiatives for the first time in the Association's history.

## REPORT OF INDUSTRY INSTITUTES INTERACTION COMMITTEE

Dr. Shrenik Shah, Chairman of the Industry Institutes Interaction Committee nominated Mr. Probhas Bondu Chakraborty and Dr. George A Patani as Vice Chairman of the Committee.

### NIPER Council Meeting : 7th April 2025

The Second NIPER Council Meeting was held on 7th April 2025 under the Chairmanship of Shri J. P. Nadda to deliberate on strategic initiatives for strengthening pharmaceutical education and research in India. The meeting focused on improving coordination among the seven National Institutes of Pharmaceutical Education and Research (NIPERs) and aligning their activities with national R&D objectives, particularly in the post-COVID context. The Council reviewed the current status of all seven NIPER institutions and underscored the need for closer collaboration to bridge the gap between academic research and commercial application. It was noted that while approximately 450 patents have been filed by NIPERs and only two have been commercialized so far. This highlighted the need to strengthen industry–academia partnerships to enhance translation of research outcomes into marketable products.

The meeting concluded with an emphasis on removing existing bottlenecks affecting research progress and commercialization. The Chair also proposed instituting biannual Council meetings to regularly review progress and ensure timely implementation of initiatives. These measures aim to reinforce India's global leadership in pharmaceutical R&D and foster sustained innovation in the sector.

### Meeting to facilitate industry/ Academia collaboration to promote R&D

A virtual meeting was organized by the Department of Pharmaceuticals (DoP) on 21st April 2025 with the objective of strengthening collaboration between industry and academia to promote pharmaceutical research and development.

Mr. Probhas Bondu Chakraborty, Vice Chairman, attended the meeting and highlighted that IDMA has an ongoing and constructive engagement with NIPER Kolkata. With a view to expanding such collaboration across all NIPERs, he requested that each NIPER share details of their current and forthcoming research project areas with IDMA. This would enable dissemination of information among IDMA member companies and facilitate effective matchmaking for potential joint initiatives, scale-up opportunities, and industry partnerships.

Mr. Chakraborty further mentioned that IDMA has extended full support for skilling and training initiatives and informed that a dedicated platform is being developed to institutionalize these collaborative efforts. He also suggested that NIPERs could play a significant role in supporting the pharmaceutical industry in the implementation of the Revised Schedule M. In this regard, he proposed that NIPERs assist the industry in dossier preparation and early-stage molecule research. It was suggested that such dossiers could be commercialized and made available to interested industry players for further development and manufacturing.

**IDMA Delegation Visit to NIPERs**

**NIPER Ahmedabad (Gandhinagar)**

Dr. Shrenik Shah led an IDMA delegation to NIPER Ahmedabad (Gandhinagar) on 22nd August 2025 to assess the institute's infrastructure, research capabilities, and potential collaboration models. The visit was aimed at strengthening industry–academia partnerships and supporting the Indian pharmaceutical industry's objectives of self-reliance and innovation. During the interaction, Ms. Neha Thakore highlighted that NIPER Ahmedabad is open to multiple modes of engagement with industry. These include joint technology development, technical consultancy, proof-of-concept (PoC) development, analytical services and support for advanced research initiatives such as gene therapy, medical device implants, laser therapy and complex molecular analysis. She emphasized that this flexible, solution-driven approach enables NIPER Ahmedabad to closely align with the evolving needs of pharmaceutical companies.

**NIPER Hyderabad**

Dr. Shrenik Shah led a delegation of IDMA members including Telangana State Board members for a meeting at NIPER Hyderabad on 17th September 2025. The primary objective of the visit was to foster collaboration between the pharmaceutical industry in Telangana and academic institutions for mutual growth and knowledge exchange. NIPER Hyderabad offers state-of-the-art laboratory facilities that provide students with hands-on exposure to advanced techniques critical for drug discovery research. Dr. George Patani highlighted that NIPER Hyderabad regularly organizes National and International seminars and workshops, offering students exposure to the latest developments in pharmaceutical sciences. He further mentioned that eminent experts from both industry and academia frequently engage with the institute, ensuring strong alignment with the evolving needs of the pharmaceutical sector.

**Indian Institute of Chemical Technology (IICT), Hyderabad**

The IDMA delegation visited the Indian Institute of Chemical Technology (IICT) on 17th September 2025 before their meeting with NIPER Hyderabad where discussions were held with the institute's leadership. The interaction resulted in productive deliberations on potential areas of collaboration between industry and research institutions.

**IDMA and Manipal University jointly celebrated the 3rd National cGMP Day on 10th October 2025 at Manipal University**

IDMA and Manipal University jointly celebrated the 3rd National cGMP Day on 10th October 2025 at Manipal University. Mr. Bharat Shah National President and Ms. Aditi Kare Panandikar, Hon. General Secretary, represented IDMA at the Manipal cGMP Forum 2025, which was organized by the Centre for cGMP, Manipal Academy of Higher Education (MAHE) in association with IDMA, Pharmexcil, and FOPE.

The National Conference on cGMP and compliance brought together distinguished industry leaders, academician and regulators to deliberate on key aspects of quality, good manufacturing practices and regulatory excellence. Ms. Aditi Kare Panandikar delivered a powerful and impactful Keynote Address, which was highly appreciated by all participants.

The key highlights of the event included the release of the *Centre for cGMP Newsletter* (Vol. 2, Issue 2), the presentation of the National cGMP Day Award 2025, and several technical sessions, poster presentations, and networking interactions among participants. A *Special Postal Cover* was also released to generate nationwide awareness on the importance of current Good Manufacturing Practices (cGMP) and the quality of medicines. In line with IDMA's ongoing commitment to promote a culture of quality and compliance, IDMA actively encouraged its member companies and affiliated institutions to participate in the initiative through pledges and training programs. These collective efforts resulted in over 3,000 cGMP pledges and more than 40 training sessions being conducted across India.

**Academia–Industry Meet**

Mr. Sanchit Chaturvedi, Chairman, IDMA Gujarat State Board shared details of two significant initiatives undertaken recently to strengthen academia–industry collaboration and support student development in the pharmaceutical sector. He informed the members that Dr. Shrenik Shah, Chairperson, Industry Institutes Interaction Committee spearheaded the meetings.

***Mega Pharmacy Placement Fair 2025*** was organized by Saraswati Institute of Pharmaceutical Sciences (SIPS), Gandhinagar, in association with IDMA-GSB, on 14th June 2025. The fair was designed to provide final-year D. Pharm, B. Pharm, M. Pharm and Pharm. D students with direct access to leading pharmaceutical recruiters. The event witnessed participation from 21 companies

offering 510 vacancies across diverse domains including R&D, QA, QC, Production, Regulatory Affairs, Medical Coding, and Marketing. More than 900 students from 68 colleges attended, resulting in 395 shortlisted candidates, with some receiving multiple offers.

Mr. Sachit Chaturvedi said that this initiative not only created tangible employment opportunities but also provided students with invaluable interview exposure and industry interactions, generating high satisfaction among recruiters and participants alike.

***Academia–Industry Meet*** was held on 10th July 2025 at L.M. College of Pharmacy, organized by APTI-Gujarat with the support of IDMA-GSB and guided by the Industry Institute Interaction Committee under the Chairmanship of Dr. Shrenik Shah. The meeting brought together 65 principals and Deans from pharmacy colleges across Gujarat, aimed at building stronger bridges between academia and industry. During the discussions, Mr. Sanchit Chaturvedi emphasized the importance of integrating practical knowledge into curricula and ensuring continuous faculty training to meet evolving industry requirements. A core committee was proposed under the "Teaching the Teachers" initiative, through which industry experts will regularly update faculty on current trends and technologies, enabling knowledge transfer to students. He said that Academia representatives also urged for greater industry support in research collaborations, placements, mentorship, and internships. The event was well-received, with participants acknowledging it as a significant step toward deeper, sustained engagement between academia and industry.

**IDMA representatives for the Department of Pharmaceuticals (DoP) committees**

1. **NIPER Academia–Industry Coordination Committee**

   - **Dr. Shrenik Shah**, Director, Montage Laboratories Pvt. Ltd.**,** IDMA Chairman of Industry Institutes Interaction Committee

2. **DoP Sub-Committees**

   - **Research and Consultancy: Dr. George Patani,** Director, INGA Laboratories P. Ltd., Sr. Vice President IDMA & Vice Chairman of Industry Institutes Interaction Committee, IDMA
   - **Regular Study: Mr. J. Jayaseelan**, MD, Sai Mirra Innopharm Pvt. Ltd. and Chairman of PR Committee, IDMA
   - **Continuing Education and Training: Mr. Probhas Bondhu Chakraborty,** MD, Mendine Pharmaceuticals Pvt. Ltd. and Vice Chairman of Industry Institutes Interaction Committee, IDMA
   - **Chief Industry Coordinator and Industry–Institute Cell: Dr. Shrenik Shah**, Director, Montage Laboratories Pvt. Ltd. and Chairman of Industry Institutes Interaction Committee, IDMA.

## REPORT OF INTERNATIONAL TRADE COMMITTEE

Mr. Sundeep Bambolkar, Chairman of the International Trade Committee mentioned that the committee was actively engaged with the Department of Pharmaceuticals (DoP) and other stakeholders to address regulatory barriers, support India's pharmaceutical exports and provide industry inputs for bilateral, regional and multilateral trade negotiations. Mr. Bhavin Mehta was nominated as the Vice Chairman of the Committee.

### India–UK Trade Agreement

The Department of Pharmaceuticals organized an virtual meeting on 8th May 2025 with regard to the India–UK Trade Agreement. The meeting was chaired by Ms. Palka Sahni, Joint Secretary, DoP and the participants were representatives from the Centre for Domestic Economic Policy, IPA, OPPI, and IDMA. IDMA highlighted that only a summary of the public document of the FTA was available and emphasized the need for access to detailed provisions, particularly those related to Chapter 29 and the pharmaceutical annexure, which was yet to be shared. IDMA underlined the successful collaboration between the Government and industry during the COVID-19 pandemic and recommended adopting a similar coordinated approach for advancing the India–UK trade framework. It was noted that India's pharmaceutical exports to the UK are approximately USD 780 million (2024–25) against the UK's total pharma imports of about USD 20 billion, indicating substantial untapped potential. Ms. Palka Sahni acknowledged the need for unified efforts and proposed developing a single industry platform, assuring that the framework and outline would be shared shortly for stakeholder inputs.

### Export Issues in Various Countries Highlighted by IDMA

### Thailand

IDMA submitted its concerns to DoP with regard to DoP's email dated 1st May 2025 to improve market access for Indian exporters. Key issues included prolonged registration timelines of 3–4 years, mandatory local bioequivalence studies, absence of fast-track approvals for SRA-approved products, language barriers on Thai regulatory portals, and lack of transparency regarding dossier status. IDMA recommended time-bound approvals, acceptance of overseas BE data, fast-track mechanisms, bilingual portals, and publication of dossiers under review.

### Malaysia

IDMA submitted its inputs on 10th May 2025 highlighting regulatory challenges such as mandatory NPRA approval of CROs despite SRA recognition, requirement of comparative dissolution studies using Malaysian reference innovators, insistence on COPP for products not marketed in India, and approval timelines exceeding three years. Lifecycle management challenges, including extensive stability data requirements for variations and barriers to post-approval changes, were also emphasized.

**Inputs for Market Access and Trade Negotiations**

The Committee provided extensive inputs to DoP on enhancing pharmaceutical exports and collaborations with Australia, Mauritius, Vietnam, and Russia, as well as for ongoing FTA negotiations with Australia, New Zealand, Namibia, Romania, and Japan.

**IDMA Submitted Inputs on the following**

1. BRICS Summit discussions covering Brazil, Argentina, Uruguay, Trinidad & Tobago, and Morocco
2. Market-specific inputs for Uzbekistan, Singapore, Fiji, and for the 7th Hungarian–Indian Joint Commission on Economic Cooperation (JCEC)
3. The 19th India–Bulgaria Joint Commission for Economic, Scientific and Technical Cooperation (JCESTC)
4. Additional country inputs including Angola, South Africa, Bhutan, Poland, Greece, Myanmar, Canada, Nepal, Venezuela, and Thailand, as sought by DoP

**India–EU Rules of Origin (RoO)**

DoP sought IDMA's inputs on the RoO provisions under the ongoing India–EU Trade Agreement negotiations. Discussions cover pharmaceuticals and allied products such as enzymes, sorbitol, and mannitol. IDMA highlighted the absence of tariff flexibility for pharmaceutical products, placing India at a disadvantage, and urged inclusion of intermediates such as Glutathione (GSH) under preferential tariff treatment. Industry engagement was emphasized as critical to safeguarding India's interests.

**Emerging Opportunities**

Members were informed about encouraging developments from Ethiopia, where regulatory authorities, supported by the World Bank, expressed willingness to grant product approvals within 48 hours without plant inspection, particularly for products already approved by USFDA or EU authorities. Given Ethiopia's large population and proactive regulatory approach, members were encouraged to explore this opportunity.

Overall, the International Trade Committee played a proactive role throughout 2025 through representations and numerous inputs and suggestions, effectively representing industry concerns, supporting the Department of Pharmaceuticals (DoP) in international negotiations and facilitating improved global market access for Indian pharmaceutical companies.

# REPORT OF IPR COMMITTEE

## Meeting to discuss the "GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

Dr. Gopakumar G Nair, Chairperson of the Intellectual Property Rights (IPR) Committee chaired the IPR Committee meeting on 12th February 2025 to deliberate on the proposed Guidelines for Submission of Applications for Patent Awards for the Year 2026.

Dr. George A Patani, Sr. Vice President, IDMA mentioned that IDMA has consistently encouraged its member companies to file Patents and foster a culture of innovation. In previous years, the Association recognized not only outstanding patents but also participation through multiple award categories. However, he emphasized that member companies have now reached a level of maturity where the focus should progressively shift from the quantity of submissions to the quality of patents.

In this context, it was proposed that while earlier guidelines permitted the submission of patent families, going forward, member companies would be requested to submit only one or two of their best patents for award consideration. This strategic change aims to raise the benchmark and further enhance the overall quality of submissions received. It was noted that although the revised policy will be implemented from the next award cycle, the Association intends to prepare members in advance by clearly outlining the revised expectations and submission framework.

The meeting acknowledged and appreciated Dr. Gopakumar Nair for chairing the discussion and providing valuable guidance in shaping the proposed guidelines. The finalized guidelines will be published in the IDMA bulletin at an appropriate stage to brief member companies to the new guidelines in the patent award submission process.

## IDMA Webinar on Recent Developments in Patents & Trademarks in Pharmaceutical Industry

The IPR Committee of IDMA under the Chairmanship of Dr. Gopakumar G. Nair organized a webinar titled "Recent Developments in Patents & Trademarks in the Pharmaceutical Industry." on Tuesday, 8th July 2025, from 4:00 PM to 6:00 PM.

The webinar facilitated engaging and insightful discussions covering the evolution of Intellectual Property Rights, IDMA's role in promoting IPR awareness, and several critical IPR issues impacting the pharmaceutical industry.

Dr. Gopakumar G. Nair delivered a comprehensive presentation titled "History of Patents and the Way Forward for India." His presentation provided an in-depth overview of the evolution of the patent regime and outlined strategic recommendations aligned with India's pharmaceutical ecosystem.

Ms. Shristi Singhania, Partner, Singhania & Co., made a presentation on "Recent Developments in Trademarks in the Pharma Industry." The session offered practical insights and key legal updates relevant to brand protection and trademark enforcement.

The webinar featured a thought-provoking panel discussion, moderated by Dr. Gopakumar G. Nair, with distinguished panelists Mr. Krishan Singhania, Ms. Shristi Singhania, Ms. Smita Prajapati, Dr. Srividya Ravi and Mr. Sajeev Kumar S. Nair. The panel shared diverse perspectives on emerging challenges and opportunities in the intellectual property landscape with particular focus on regulatory trends, litigation, biosimilars and counterfeiting.

**DoP Inputs on Commerce - Permanent Mission of India to the WTO Side event on "TRIPS implementation and Public Health and the TRIPS**

Dr. Gopakumar G. Nair informed the members that the Department of Pharmaceuticals (DoP) had sought inputs from industry experts on India's key priorities at the intersection of public health and the TRIPS Agreement, particularly in the context of ongoing Free Trade Agreement (FTA) negotiations with countries such as the United Kingdom and the United States of America. He explained that Article 8 of the TRIPS Agreement provides member countries with the flexibility to adopt measures necessary to protect public health. However, he observed that, in practice, these TRIPS flexibility have not been adequately or effectively implemented.

Dr. Gopakumar G. Nair emphasized that India has recommended strengthening both the language and interpretation of Article 8 to explicitly recognize the primacy of public health over intellectual property protection, consistent with the principles laid down in the Doha Declaration on the TRIPS Agreement and Public Health.

He said that India's position is firmly focused on ensuring that TRIPS implementation remains public health–oriented, thereby safeguarding access to affordable medicines and supporting the domestic pharmaceutical industry's ability to meet national and global public health requirements.

**IDMA's inputs with regard to India-EU Rules of Origin**

The Department of Pharmaceuticals (DoP) had sought industry inputs on the Rules of Origin (RoO) provisions under the ongoing India–European Union Trade Agreement negotiations. Similar discussions had earlier been initiated under the India–UK FTA, progress on that front was presently been kept in abeyance.

Dr. Gopakumar G. Nair stated that the India–EU negotiations are currently active, with detailed deliberations covering key pharmaceutical and allied products, including enzymes, sorbitol, and mannitol. The principal focus areas under discussion include tariff classification, origin eligibility criteria, and preferential duty treatment. He mentioned that under the existing framework, pharmaceutical products do not enjoy tariff flexibility, which places India at a

comparative disadvantage vis-à-vis other exporting countries. In this regard, he mentioned that the Indian Chemical Manufacturers Association (ICMA) and other industry bodies have strongly urged negotiators to include “GSH” (Glutathione) and other relevant intermediates within the pharmaceutical product category for preferential tariff treatment.

Dr. Gopakumar G. Nair mentioned that the language and technical aspects of the RoO provisions are still under discussion and are expected to be finalized in the near term. He emphasized the critical importance of continued industry engagement to ensure that India’s interests particularly in pharmaceuticals and intermediates are adequately safeguarded during these trade negotiations.

**Stakeholders Consultation with Hon’ble Secretary DPIIT on Regulatory Data Protection (RDP)**

A Stakeholder Consultation Meeting on Regulatory Data Protection (RDP) with the Hon’ble Secretary, DPIIT, Shri Amardeep Singh Bhatia, was held at Vanijya Bhawan, New Delhi on 19th November 2025. IDMA was represented by Mr. Mahesh Mahadgut, Vice Chairperson, IDMA IPR Committee and Mr. Ashok Madan, Executive Director, IDMA Delhi Office.

Mr. Mahesh Mahadgut briefed the members that the consultation was chaired by the Secretary, DPIIT, who underscored the need to explore a balanced, practical and tiered RDP framework that safeguards innovation while addressing industry concerns. He emphasized the critical importance of regulatory data in the pharmaceutical sector, noting the significant scientific effort, financial investment and regulatory scrutiny involved in its generation. Prior to finalizing any RDP framework, it is essential to fully appreciate the value of such data and assess the implications of permitting reliance by subsequent applicants.

Mr. Mahesh Mahadgut explained that pre-approval regulatory data lies at the core of the RDP debate. Once marketing approval is granted, the underlying data becomes vulnerable to potential misuse unless appropriate safeguards are instituted. In this context, he suggested that a defined lock-in period of 3–5 years for reliance on such data by subsequent applicants could be considered. He further observed that while data exclusivity models exist internationally, India’s current regulatory and industry ecosystem may not be fully prepared for the immediate adoption of a comprehensive RDP regime. He recalled that discussions on RDP were previously held in 2013, 2015 and 2023, during which the pharmaceutical industry consistently expressed strong opposition, unlike the agro-chemicals sector, which supported RDP due to its distinct regulatory environment. He cautioned that any policy decision must be aligned with Section 3(d) of the Patents Act, failing which could lead to evergreening. Over time, it has become evident that the pharma and agro-chemical sectors cannot be governed under a common framework and accordingly, the present consultation focused on pharma-specific approaches.

During the consultation, DPIIT invited industry representatives to share views on appropriate timelines should India adopt an RDP framework. Industry suggestions included:

- Innovators should be required to file in India within 6 months to 1 year of receiving the first foreign approval.
- Indian regulatory processing timelines should remain independent of this filing requirement.
- A 2–3-year data protection period may be considered, commencing from the date the first applicant receives approval in India.

Mr. Mahesh Mahadgut further explained that innovators typically commence commercialization immediately after receiving first global approval, while Indian market entry often occurs four years or later. For products enjoying long patent terms (17–20 years), it becomes critical to define the reference date for data protection in India. A mandatory filing timeline for innovators is therefore essential to prevent strategic delays in Indian submissions.

Ms. Aditi Kare Panandikar highlighted that delays in filing could adversely affect Indian companies' ability to participate in U.S. first-to-file (FTF) opportunities, where 180-day exclusivity is of high strategic value. She cautioned that restricting access to reference data could impede comparative studies and bioequivalence evaluations, thereby disadvantaging Indian manufacturers in global markets.

She raised a key concern on whether RDP would hinder Indian companies from participating in U.S. FTF opportunities, noting that Indian manufacturers typically begin development well before innovators file in India, relying on reference products and comparative data for:

- ANDA submissions
- Bioequivalence studies
- 180-day Exclusivity filings

If regulatory data in India were to remain inaccessible for extended periods, companies may be unable to generate requisite comparative data in time, potentially resulting in the loss of critical FTF opportunities. She stressed the need to carefully balance innovation protection with the global competitiveness of Indian generic manufacturers.

Dr. Viranchi Shah stated that the fundamental question is whether India requires RDP at all, or whether alternative mechanisms could adequately address innovator concerns without harming the domestic pharmaceutical industry. He noted that while Europe follows an 8 + 2 + 1 data and market exclusivity model and China provides six years of data protection, each jurisdiction has tailored its approach to national priorities. India's primary objective should be to avoid or minimize RDP, provided innovator interests can still be protected. Dr. Viranchi Shah cautioned that adopting a Chinese-style six-year RDP period could effectively operate as a patent-term extension, delaying generic entry and adversely impacting Indian manufacturers. Any proposal must therefore be evaluated through the lens of affordability, access to medicines, and domestic industry competitiveness.

Dr. Gopakumar G. Nair noted that RDP discussions have resurfaced repeatedly in 2013, 2015, and 2023, yet the pharmaceutical industry's core position has remained unchanged. He suggested that if India were to adopt a data protection framework, it must be clearly recorded that the protection period should commence from the first approval in a regulated market such as the U.S., Switzerland or Germany. He opined that a four-year global data protection period, counted from the first international approval, would not adversely affect Indian generic development. Indian companies typically initiate generic development two years prior to patent expiry, relying on publicly available information such as the U.S. FDA Orange Book, while Indian regulatory approvals usually occur much later. Consequently, such an approach would not disrupt existing development timelines.

Dr. Gopakumar G. Nair concluded that stakeholders appear to be gradually converging on the understanding that India and the U.S. operate under different regulatory timelines and therefore India must adopt an India-specific RDP model aligned with the Drugs and Cosmetics Act, ensuring that generic market entry is not impeded. He reiterated that a four-year data protection period, calibrated to Indian regulatory realities, could be workable and manageable for the industry.

## REPORT OF MEDICAL COMMITTEE

### First Medical Committee Meeting

The first meeting of the Medical Committee for the year 2025–26 was held at the IDMA Office on 25th March 2025.

Dr. Mahesh Abhyankar assumed charge as Chairperson of the Medical Committee for the term 2025 & 2026 and under his leadership, the Committee decided to adopt a proactive and structured approach to address evolving pharmaceutical industry requirements with particular emphasis on medical education, regulatory awareness and pharmacovigilance through focused and outcome-driven initiatives in line with IDMA's objectives.

### Second Meeting of the Medical Committee

The Second Meeting of the Medical Committee was held on May 29th, 2025, at the IDMA Office to deliberate on the follow-up action plan arising from the discussions and outcomes of the first meeting of the Committee.

The Committee proposed the launch of a **structured webinar series** aimed at professionals from the **medical, insurance and pharmaceutical marketing sectors**. The initiative is intended to promote cross-functional interaction and facilitate meaningful exchange of knowledge on issues of common relevance across these domains. It was further informed that the proposed series would consist of six-monthly **webinars**, tentatively scheduled to be held in the **third week of each month**. The topics would be carefully curated to address **contemporary challenges, emerging trends, and developments** pertinent to the respective sectors.

**Two Webinars in 2025**

Dr. Mahesh Abhyankar launched the **webinar series on medico-marketing topics** aimed at disseminating scientific knowledge and upskilling pharmaceutical professionals. Each session follows a structured format comprising a 10-minute keynote, a panel discussion with 3–4 experts, and an interactive Q&A.

**The first webinar** titled **"Real World Evidence – Brand Strength to Dominance"** featured Dr. Mahesh Abhyankar, Dr. Abhijit Trailokya, Dr. Sachin Suryavanshi and Dr. Khokan Debnath as Panellists. The session emphasized the strategic role of Real World Evidence (RWE) in brand growth and differentiation, highlighting that RWE from India can enhance trust among healthcare professionals, patients, and consumers while strengthening India's global image.

**The second webinar - "Bridging the Gap Between Patients and HCPs: Challenges and Opportunities for Indian Pharma"** featured Dr. Mahesh Abhyankar, Dr. Amit Qamra, Mr. Nikhil Dhamne and Mr. Thamburaj. It focused on how pharma companies can strengthen HCP–patient relationships through improved adherence, communication, and digital innovations across all stages of the patient journey.

**Campus to Corporate Session at IES Management school, Bandra**

- Theme: Campus to Corporate Session- focused on pharma
- Dates: 3 sessions in October and November (2 hours)
- Focus: Skills for corporates
- Facilitator: Dr. Mahesh Abhyankar

**IDMA Medical Committee Collaboration in 5th Global Medical Affairs Conference (GMAC 2025)**

- Theme: "Where Science Meets Strategy: The Future of Medical Affairs"
- Dates: 20th & 21st December 2025
- Venue: Dr. D. Y. Patil University, School of Medicine, Nerul, Navi Mumbai
- Organized by: RENOVARE Healthcare Solutions, Partner IDMA

Key Outcomes of conference

- Reinforced the strategic and leadership role of Medical Affairs
- Highlighted AI, data science, and digital innovation as core enablers
- Strengthened best practices in evidence generation, publications, and compliance
- Inspired future leaders through career-focused discussions
- Enhanced collaboration across industry, academia, and healthcare stakeholders

IDMA appreciates and thanks Dr. Mahesh Abhyankar and his Medical Committee team for successfully organizing the events. Each meeting was witnessed participation from over 200 professionals across the medical, marketing and research domains, making them highly impactful and successful. The Medical Committee is collaborating with the Pharma in Future platform by Lifecom Scientia to continue this initiative in the next year.

## REPORT OF MEMBERSHIP & CONSTITUTION COMMITTEE

### Members' Annual Turnover Data

Mr. Mahesh Doshi, Chairman of the Membership & Constitution Committee of IDMA, mentioned that Mr. Mehul Shah had assisted the Association in obtaining data pertaining to the Annual Turnover of members from a very reliable source/organization. Mr. Mehul Shah stated that IDMA is in the process of upgrading its Tally Accounting Software and the said data will be incorporated into the Tally system. This will facilitate the preparation of proforma invoices based on the actual turnover of members. Mr. Bharat Shah, National President along with the Executive Committee Members appreciated the efforts and contributions of Mr. Mahesh Doshi and Mr. Mehul Shah as this was the first time in the history of IDMA that such an initiative was successfully undertaken.

### Membership Fees – Proposal for Rationalization & Simplification

Mr. Mehul Shah proposed the rationalization and simplification of the Membership Fee Structure for the forthcoming financial year with the objective of strengthening the financial health of the Association.

The key highlights of the proposed revised membership fee structure are as follows:

- Revision of the membership fee structure after a gap of five years (last revised in 2020).
- The Finance Committee recommended rationalization of the existing fee structure by reducing the number of slabs from ten to five.
- Introduction of an additional slab for organizations with an annual turnover exceeding INR 500 crore.
- For Associate Members, it was proposed to reduce the number of slabs from seven to four.
- It was recommended to merge the existing 20% surcharge into the membership fee structure itself.
- The proposed changes intends to improve the long-term financial sustainability of IDMA.

Members from some of the State Boards expressed their reservations regarding the proposal. After deliberations, it was agreed to hold separate meetings with all State Boards to discuss the proposed membership fee structure.

Mr. Mahesh Doshi assured the members that he would rework the Membership Fee Structure in consultation with Mr. Mehul Shah and all the State Boards and then present the revised proposal at the next Executive Committee Meeting.

**Membership Strength**

In the year 2025, IDMA's membership strength at the year-end stood at 1245 members. Mr. Mahesh Doshi informed the members that with the sustained efforts of the IDMA State Boards and the IDMA Secretariat, a total of 85 new members were enrolled during the year. These included 5 Corporate Members, 47 Principal Members, 21 Associate Company Members, and 12 Associate Academic Members. A total of 64 members were removed from IDMA's membership due to non-renewal of membership fees for more than three years.

Mr. Mahesh Doshi appreciated and thanked Mr. Bharat Shah, National President, Mr. Mehul Shah, Vice President (Western Region) and the Chairmen, Vice Chairmen and Secretaries of all State Boards for their continued support, coordination and cooperation throughout the year in strengthening IDMA's Membership.

## REPORT OF MSME COMMITTEE

**IDMA Support to MSME Members**

IDMA has launched a **non-commercial support initiative** to assist MSME pharmaceutical companies in complying with the revised **Schedule M** requirements. Under this initiative, a panel of Senior industry experts provides guidance on **GMP compliance, quality systems, and facility upgradation**, with only a nominal registration fee. A circular in this regard was issued on **11th February 2025** to all IDMA Members.

**Support Initiatives and regulatory engagements on Revised Schedule M & ONDLS**

**Central Drugs Standard Control Organization (CDSCO)** conducted a **virtual conference on 14th February 2025** to deliberate on the **extension of implementation timelines for the revised Schedule M** and to provide a **live demonstration on filing applications for extension through the ONDLS portal**.

The meeting was chaired by **Dr. Rajeev Singh Raghuvanshi, DCGI**, and supported by **Mr. Ranga Chandrashekhar, Joint Drugs Controller of India**. During the discussions, **Mr. S. M. Mudda**, representing IDMA, highlighted industry concerns, particularly the practical challenges and feasibility issues associated with implementing **air locks in existing manufacturing facilities**. Detailed deliberations were also held on the ONDLS portal, and IDMA suggested that **additional training or demo sessions** be conducted to enhance clarity and ease of use for stakeholders.

In continuation of capacity-building efforts, a **Training Session on the Online National Drug Licensing System (ONDLS)** is being organized by **CDSCO West Zone**, in collaboration with **IDMA and FDA Maharashtra**, on **Monday, 23rd June 2025**, from **9:30 AM to 5:00 PM** at **Jade Ballroom, Nehru Centre, Worli, Mumbai**.

The Training Session was led by the newly appointed **CDSCO West Zone Head, Dr. Santosh Indraraksha**, along with technical experts from **CDAC**. Approximately **166 participants have already registered** for the program. IDMA has also arranged a **hybrid participation option** and encouraged member companies, particularly those based in Mumbai, to take advantage of this valuable learning opportunity.

**Grant of WHO-GMP COPP through ONDLS Portal: Extension request**

**CDSCO issued a circular dated 25th June 2025**, directing all **State Drugs Controllers** to ensure that applications for **WHO-GMP (COPP)** approvals are submitted **exclusively through the ONDLS portal** with effect from **15th July 2025**.

To familiarize stakeholders with the online application process, CDSCO organized a hybrid demonstration meeting chaired by Mr. R. Chandrashekar, Joint Drugs Controller (India). The session received an overwhelming response, with over 1,000 participants attending online, while more than 1,000 additional interested participants were unable to join as the session had reached full capacity.

During the interaction, several operational and procedural queries were raised by participants. **IDMA also raised multiple concerns** and formally **requested an extension of the timeline** for implementing the digitized WHO-GMP COPP application process, considering the scale of transition and stakeholder preparedness.

Subsequently, **CDSCO issued a circular on 15th July 2025**, granting an **extension for submission of WHO-GMP COPP applications through the ONDLS portal up to 15th August 2025**.

**IDMA Representation - Grant of WHO-GMP COPP through ONDLS portal**

IDMA submitted a representation on 11th July 2025, highlighting that the grant of **WHO-GMP/COPP is critical for registration of pharmaceutical products in global markets**. While appreciating the initiative to implement the **Online National Drug Licensing System (ONDLS)** as a unified national platform, IDMA emphasized that successful rollout requires adequate training, system readiness, and resolution of operational challenges. Although training sessions conducted by CDSCO and CDAC on **13th August 2025** were helpful, both manufacturers and State Licensing Authorities are still in the process of familiarizing themselves with the system.

IDMA pointed out several operational concerns, including the **complex and time-consuming process of entering legacy licence data**, lack of integration with **Sugam and XLN portals**, absence of **field-level error correction**, rigid contact information requirements for multiple sites, and **role conflicts** arising from assigning regulatory responsibilities to manufacturing chemists. Additional issues such as mandatory shelf life and pack size at the application stage, technical glitches, lack of application status tracking, and undefined processing timelines were also highlighted.

In view of these challenges, IDMA recommended **deferring the ONDLS rollout for WHO-GMP/ COPP**, enabling data integration, allowing flexible contact details, permitting post-approval changes, introducing application tracking with defined timelines, and adopting a **phased implementation approach** to avoid disruption in the issuance of WHO-GMP/COPP certificates.

### Meeting on registration of PRIP application form

During the virtual meeting on registration of the **PRIP (Promotion of Research and Innovation in Pharma MedTech)** application form, it was noted that the Government has finalized and rolled out the PRIP scheme, which has undergone **significant changes from the original proposal** circulated through the EOI process. Ms. Aditi Panandikar informed that she met **Mr. Vikash Agrawala of Boston Consulting Group** to convey IDMA's concerns regarding these deviations. She explained that the earlier three-tier structure (B1, B2, B3) has been replaced with three broad categories covering **New Drugs and Biologics**, **Complex Generics and Biosimilars**, and **Medical Devices**, with projects now classified under **Technology Readiness Levels (TRL 1–9)**.

Under the revised funding norms, **only startups and MSMEs are eligible for TRL 1–3**, with full funding capped at ₹**1 crore**, excluding larger companies at the ideation stage. For **TRL 4–9**, larger companies may apply but are eligible for only **35% funding**, capped at ₹**35 crore**, which is a significant reduction from the earlier proposal of 75% support. Soft forms for TRL 4–6 are open, the application process is **highly detailed and intrusive**, requiring disclosure of sensitive information for relatively limited funding.

Six webinars were conducted in October to explain the revised scheme and application process. **Despite the positive intent to promote innovation**, the revised structure, restrictive eligibility criteria, and reduced funding limits make the scheme **impractical for meaningful participation** by both MSMEs and large pharmaceutical companies.

## REPORT OF NDPS COMMITTEE

### Meetings with Narcotics Control Bureau (NCB) Officials on 28th & 29th November 2024

IDMA's NDPS Committee Chairman Mr. Devesh Malladi led a delegation to New Delhi and held meetings with the following NCB officials:

- Shri. Anurag Garg, Director General, NCB.
- Shri. Anand Prakash Tiwari, Deputy Director General (Special Wing).

The delegation included Mr. Anurag Khera from Glenmark, Mr. Amit Chaudhary from Jubilant and Mr. Abhijeet Kamasamudram from Synthimed.

The discussions were focused on three critical issues affecting the industry concerning controlled substances. During the meeting, Mr. Devesh Malladi delivered a presentation on behalf of IDMA, outlining the concerns and potential resolutions.

The key outcome of the meetings was the suggestion from NCB that industry Associations should engage a software provider to develop a dedicated web portal. This portal would facilitate online registration, return filing, and compliance with procedures mandated under the RCS Order, 2013. IDMA's vision of a digital and streamlined system aligns well with modern regulatory compliances.

IDMA submitted a written representation to the DG, NCB, requesting to expedite action on the issues discussed during the meeting on 28th November 2024.

**High-level Meeting with the Office of National Drug Control Policy (ONDCP), White House, held at the Torrent R&D Centre in Gandhinagar**

A high-level meeting with the Office of National Drug Control Policy (ONDCP), White House, was held at the Torrent R&D Centre in Gandhinagar on 12th August 2025. Dr. Viranchi Shah led the industry delegation on behalf of IDMA and IPA. The main objective of the U.S. delegation's visit to India was to discuss challenges related to supply chain of drugs/precursor chemicals and explore collaboration with the Indian pharmaceutical industry and authorities to ensure better oversight, particularly for precursors exported to the United States. The list of attendees were as follows:

| List of attendees | | | |
|---|---|---|---|
| **Sl. No** | **Name** | **Designation** | **Representative of** |
| 01 | DEBBIE W. SEGUIN | Asst Director | ONDCP – EOP |
| 02 | KURT SHULKITAS | Senior Policy Analyst | ONDCP – EOP |
| 03 | DR. MICHAEL MCCORMICK | Chemist | ONDCP – EOP |
| 04 | KATIE A DORAIS | Asst Specialist | FDA, Delhi – US Embassy |
| 05 | GREGORY SMITH | Country Director - India | FDA, Delhi – US Embassy |
| 06 | PRIYANKA VISARIA – NAYAK | Political Advisor | US Embassy, Mumbai |

| | | | |
|---|---|---|---|
| 07 | SANGEETA TANEJA | Sr. Commercial Specialist & Office Director | US Embassy, Ahmedabad |
| 08 | GAURAV SACHAK | President & Head – Global Demand, Supply Org & IT | IPA |
| 09 | ASHISH HAJARNIS | Executive Director | IPA |
| 10 | GAGAN BHARADWAJ | Chief Supply Chain Officer | IPA |
| 11 | HEMAL G PATEL | VP (Corp Relation) | IPA |
| 12 | PRASHANT KANE | Sr. VP – R&D Operations | IPA |
| 13 | DR VIRANCHI SHAH | Immediate Past National President | IDMA |
| 14 | DEVESH MALLADI | Managing Director | IDMA |

**Following was the gist of Industry submissions to the ONDCP delegation:**

The current legal framework for precursor chemicals in India is centered around compulsory registration of seven key precursors such as Acetic anhydride, Ephedrine & Pseudo Ephedrine as well as ANPP, NPP and import/export control for approximately 45 precursors. The legal framework involves registration of manufacturers, traders & consumers of precursor chemicals, transportation controls, maintenance of daily records for production, sale and the filing of quarterly returns with the Narcotics Control Bureau (NCB). Every import & export is undertaken with prior NOC authorization from the Central Bureau of Narcotics (CBN) after obtaining the requisite permit/authorization from the importing/exporting country. These are aligned with INCB guidelines and UN conventions.

The industry also follows a voluntary code of conduct, in case of several pre-precursors which are not scheduled (78) and voluntarily declares these to the Central Bureau of Narcotics (CBN) prior to any export of the same. In the last couple of years, the Central Bureau of Narcotics (CBN) has signed MoUs with two industry associations to implement a standard voluntary code of conduct across all precursor manufacturers, conduct workshops to raise awareness and also, encourage industry intelligence sharing with enforcement authorities. They have emphasized a zero-tolerance policy towards diversion.

Both the Central Bureau of Narcotics (CBN) & Narcotics Control Bureau (NCB) have held interactive workshops with industry participants across different Indian Cities to create awareness and sensitize the industry on the controls and encourage intelligence sharing.

Industry associations, on their behalf, have been pursuing with their member companies to embrace the voluntary code of conduct, increase Know-Your-Customer (KYC) compliance and share any relevant intelligence information that will be relevant to potential diversion to the enforcement authorities. It is our strong belief that the continued cooperation between industry and the authorities would strengthen the monitoring and traceability and prevent consequent diversion of precursors, chemical production and trade from India.

While the delegation inquired about potential direct cooperation with the industry, Mr. Devesh Malladi, Chairman, NDPS Committee clarified that it would be appropriate that this be routed through Indian narcotic authorities - NCB and CBN, as these authorities have legal enforcement right to give directions/instructions to industry vis-a-vis the industry associations. He assured the delegation that the industry was open to cooperation, along with the Indian narcotic authorities. The delegation also visited Delhi and held discussions with CII, FICCI, NCB and CBN. They highlighted concerns about other psychoactive drugs, such as Tramadol, Xylazine, which have been causing problems in the U.S.

## REPORT OF NEXT GEN COMMITTEE

### Launch of IDMA Next Gen Committee

**Mr. Bharat N. Shah**, National President, IDMA, proudly announced the formation of the **IDMA Next Gen Committee**, the committee envisioned to bring together the next generation of entrepreneurs who would play a pivotal role in IDMA's activities and initiatives. The Committee represents a strategic step towards nurturing future leadership and ensuring continuity of values within the Association.

The Next Gen Committee is led by **Mr. Niraj Mahesh Doshi** as Chairperson, with **Mr. Kunal N. Gandhi** and **Mr. Darpan Roy Chowdhury** as Vice Chairpersons. The ten-member Committee received its formal blessings during the **IDMA Annual Day Celebrations** from **Shri Piyush Goyal, Hon'ble Union Minister of Commerce**, marking a significant milestone in IDMA's leadership development journey.

### First Meeting of the IDMA Next Gen Committee

The first physical meeting of the IDMA Next Gen Committee was held to deliberate on strategic initiatives aimed at enhancing IDMA's engagement, visibility, and future-ready outlook.

**Mr. Niraj Doshi** informed the members that, with a view to strengthening IDMA's digital footprint and modernizing its outreach, the Association has been engaging with multiple digital agencies. **White Marquee** and **Ad Factor** have already presented their proposals, and discussions with additional agencies are ongoing. A consolidated evaluation report will be prepared and submitted to the Executive Committee for consideration.

Highlighting the urgency of this initiative, **Next Gen Committee** noted that despite IDMA having over **1,100 members**, its **LinkedIn following is currently around 400**, with minimal engagement on recent posts. This clearly underscores the need for a comprehensive restructuring of IDMA's digital presence to significantly improve member engagement and external visibility.

As part of the proposed digital revamp, the Committee is also evaluating the launch of an **IDMA podcast series** focused on knowledge sharing and industry insights. In addition, the Next Gen Committee is planning a **networking event in July or August 2025** for all IDMA members, with a special emphasis on Next Gen participation. A key highlight of this event will be **two fireside chats**, aimed at fostering intergenerational dialogue, inspiration, and collaboration. For this initiative, discussions are underway with **PwC**, one of the agencies under evaluation.

Mr. Doshi acknowledged that these initiatives would require substantial funding and expressed his sincere appreciation to the President for his continued support and encouragement to seek financial assistance as required, which has significantly strengthened the confidence of the Committee.

**IDMA CARES 2025 – ESG & Next Gen Initiative**

**Ms. Neha Thakore** briefed the members on **IDMA CARES 2025**, a flagship collaborative initiative of the **Next Gen Committee** and the **ESG Committee**, aimed at promoting responsible pharmaceutical leadership and progressive workplace practices. The event, themed **"Creating Accountable, Respectful, Responsible, Empowered Workspaces,"** was held on **Friday, July 18, 2025**, at **Taj Santacruz, Mumbai**.

**Next Gen Committee** requested the support of Executive Committee members in mobilizing sponsorships, registrations, and senior-level participation to ensure the success of the event and its alignment with the **Viksit Bharat vision**.

**Mr. Niraj Doshi**, formally announced that **IDMA CARES 2025** would be the Committee's **first kick-start event**, jointly organized with the ESG Committee. He emphasized that ESG practices are becoming increasingly critical for pharmaceutical companies, particularly when engaging with multinational corporations that require alignment with global ESG standards. Strong ESG frameworks support regulatory compliance, enhance global market access, and address evolving investor expectations.

The event was graced by the following dignitaries:

- Mrs. Vijaya Rahatakar, Chairperson, National Commission For Women, **the Chief Guest of IDMA CARES.**
- Dr. Anup Yadava, IAS, Secretary, Women and Child Development, Govt. of Maharashtra, **the Guest of Honour of IDMA CARES**. (Video Message)
- Ms. Kiran Mazumdar-Shaw, who emphasized building globally trusted, people-first businesses. (Video Message)
- Ms. Priyanka, who called on the industry to unlock the full potential of women, millennials and Gen-Zs our greatest untapped assets.

The event featured a **panel discussion with eminent industry leaders**, including:

- **Ms. Aditi Kare Panandikar**, Managing Director, Indoco Remedies
- **Ms. Meher Pudumjee**, Chairperson, Thermax Group
- **Mr. P.S.R.K. Prasad**, Director, Natco Pharma

Mr. Niraj Doshi also placed on record his appreciation for **Dr. Viranchi Shah** for conducting the Committee's first interview, with the support of **Express Pharma**, the media partner for the event.

**Update from Executive Committee Meeting – November 21, 2025**

At the Executive Committee Meeting held on **November 21, 2025**, Mr. Niraj Doshi informed members that the Committee is planning a visit to the **ACG Group's manufacturing facilities near Pune**. He conveyed sincere appreciation to **Mr. Ajit Singh**, Chairperson, ACG Group, for facilitating this opportunity. The confirmed date for the visit will be communicated in due course.

Mr. Doshi further apprised the Committee that the Next Gen Committee is proposing to organize a **series of webinars** on contemporary and emerging themes, including **digitalization in the pharmaceutical sector** and the **application of artificial intelligence (AI)**.

He further informed that a **session on the application of AI in the pharmaceutical industry**, in collaboration with **PwC as the knowledge partner**, will be held during the **IDMA Annual Day event in February 2026**.

## REPORT OF NUTRACEUTICAL COMMITTEE

The Nutraceutical Committee had a highly eventful and productive year in 2025 under the able Chairmanship of Dr. R. K. Sanghavi.

**SYMPOSIUM ORGANIZED**

**IDMA & VITAL NEUTRACEUTICALS Symposium on Nutraceuticals - "Is Indian Nutraceutical Industry Destined to Miss INR 1 Lakh Crore Bus for 2030?"**

The Symposium was duly supported by Vital Neutraceuticals along with 15 partnering Organizations and Institutions from the Nutraceutical Industry. This was a first time that so many partners joined hands with IDMA & Vital Neutraceuticals since the symposium was to lay threadbare the upcoming challenges to be faced by the FBOs in warding off a possibility of shifting nutrients and pre-probiotics (and subsequently the whole nutraceutical portfolio) under the ambit of drug regulators. The consequences of such a move looming on the heads of stakeholders was transparently discussed. In spite of the Symposium being held on 9$^{th}$ May 2025 in Mumbai amidst the tensions between India and Pakistan, there were over 100 participating delegates. Despite

several participants cancelling their participation due to the prevailing war-like situation, the Symposium was conducted successfully and proved to be a grand success. Mr. Ganesh Kamath of Vital Neutraceuticals, and a Vice-Chairman of IDMA's Nutraceutical Committee needs, a special mention for being rock-solid in supporting organizing the Symposium.

All the Nutraceutical Committee members as well as concerned IDMA's staff deserve to be reckoned for their efforts in ensuring smooth conduct of the Symposium.

**WHITE PAPER on Nutraceuticals**

The Nutraceutical Committee organized Symposium on 9th May 2025 titled "Is Indian Nutraceutical Industry Destined to Miss INR 1 Lakh Crore Bus for 2030?" proceedings were captured and an elaboration of topics discussed were compiled by Dr. R. K. Sanghavi as a comprehensively compiled White Paper which is being forwarded to all relevant regulators as well as the Ministries and Departments currently engaged to consider lateral shift or a merging of Nutraceuticals under the ambit of either CDSCO or AYUSH for regulating.

A meeting was held at the IDMA office on 6th August 2025 to discuss the upcoming Industry Roundtable Discussion being jointly organized by IDMA and NSF on "Navigating the Future of Nutraceutical Regulation: An Industry Roundtable on Quality, Claims & Compliance in Nutraceuticals." scheduled for 19th August 2025 at Mahogany Hall, Grand Hyatt Hotel (Mumbai). The intent was to share the draft White Paper across the table with the partnering associations and institutions as well as concerned stakeholders and decide upon the steps for formalizing white Paper and submission of the same jointly to the concerned Government officials. This collective approach is being taken to avoid fragmented practices and regulatory inconsistencies which do not align with global standards, pertaining to Nutraceutical vertical and its stakeholders.

**Looming possibility of shifting Nutraceutical health vertical or some segment of it, from under the ambit of FSSAI to either CDSCO and / or AYUSH**

Dr. R. K. Sanghavi informed that the proposal to shift the Nutraceutical and Health Supplements vertical or certain segments of it from the purview of FSSAI to either CDSCO and/or the Ministry of AYUSH is still pending, though the Government is expected to take a decision soon. He mentioned that IDMA has been actively pursuing this matter and had therefore organized the 9th May 2025 conference on the subject. He said that there is widespread discussion on this issue, even within the Ministry of Food Processing Industries (MoFPI), which is reportedly in dialogue with the PMO. He emphasized that if this transition takes place, it will be spell a death-knell for the Nutraceutical vertical of healthcare in India. During his several visits to Delhi Dr. R. K. Sanghavi, along with the Vice-Chairman, Mr. Ganesh Kamath, has met the FSSAI CEO and the MoFPI Secretaries as well as the Honorable Minister Shri Chirag Paswan and the illogic of shifting Nutraceuticals grave perils associated with the same were elaborated. The stray hope of persisting of Nutraceuticals as a separate vertical from regulatory perspective is to enable the MoFPI to fully 'own' the sector and

for this IDMA needs to support the cause from all accounts or else the latter vertical fate would be sealed since the most persuasive and knowledgeable talent rests within its own Nutraceutical Committee.

**Meeting with Mr. Ranjit Punhani, IAS, CEO FSSAI**

Dr. R. K. Sanghavi represented IDMA along with other stakeholders and SHEFEXIL and met Mr. Ranjit Punhani, CEO, FSSAI on 7th October 2025. The meeting was very brief as the CEO was occupied with other engagements. Dr. Sanghavi said that despite the limited time, he briefly apprised Mr. Ranjit Punhani, of key IDMA concerns and issues related to Nutraceuticals emerging out of the Inter-Ministerial Committee meetings set up to review 'The Regulatory Purview of Nutraceuticals'. He conveyed the need for a more detailed interaction on the burning issue of 'mixing' up of Nutraceuticals with drugs.

**Meeting on Nutraceutical under the Chairmanship of Shri Devesh Deval, Joint Secretary, MoFPI**

Dr. R. K. Sanghavi along with Mr. Ganesh Kamath, Vice Chairman, as well as Ms. Supriya Yadav, Member, Nutraceutical Committee attended a stakeholder meeting convened by Shri Devesh Deval, Joint Secretary, Ministry of Food Processing Industries, on 6th November 2025 in New Delhi to discuss issues related to the nutraceutical sector. He informed the EC members that the meeting saw participation from around 30 stakeholders and was very constructive. Dr. Sanghavi noted that Shri Deval, though new to the role, was extremely attentive, enthusiastic, and receptive to the industry's concerns. Detailed discussions were held on the proposal to shift nutraceuticals under the Drugs framework and the pitfalls if the same was to be considered. Dr. Sanghavi emphasized that such regulatory control of Nutraceuticals is not a global practice. He urged that instead nutrient products, or with nutraceutical ingredients and approved as drugs, should be moved to under the FSSAI ambit since these are meant for preventive, non-therapeutic use - rather than considering effecting the reverse. IDMA also presented a comparative table of permissible claims across regulatory bodies globally, highlighting that in particular the Disease Risk Reduction (DRR) claims are accepted worldwide and should not be insisted, or even considered, for procuring approval of such claim by the Drug Authority or the Ministry of AYUSH.

Regarding safety, Dr. Sanghavi clarified that global standards allow ingredients up to upper-limit (UL) thresholds, whereas India already follows more conservative caps based on RDA values, ensuring adequate safety. He further highlighted that 60-70% of Indian consumers purchase supplements on their own, and India's supplement consumer base at around 40% is comparable to regulated markets such as Australia and China. Given this growing market, he cautioned that restrictive regulatory moves could severely impact industry growth, including nearly 300 startups in the Nutraceutical space, potentially taking the sector back to conditions seen in the 1980s.

Dr. Sanghavi mentioned the need to proactively publish articles and engage the press to clarify misconceptions being circulated across various forums. He suggested that IDMA should allocate a dedicated budget for this communication effort, as it could possibly serve to prevent adverse outcomes and avoid future legal challenges.

**Dual-Use of Drug Facility**

Dr. R. K. Sanghavi informed the Executive Committee Members during the 17th April 2025 EC Meeting about the issues of regulatory inconsistencies, particularly the differential treatment between Nutraceuticals, Phytopharmaceuticals and Radiopharmaceuticals. While the latter two categories are allowed to be manufactured in dual-use drug facilities, Nutraceuticals, inspite of their similarity, face unnecessary restrictions. IDMA made various presentations on different Government Forums and also, Nutraceutical Committee particularly supported by its FBO member, Mr. Vivek Tannan, also made an apt representation focused on not permitting dual use of drug facility. In line with global practices, IDMA has requested the concerned authorities to permit the manufacture of nutraceuticals and similar allied products in pharmaceutical facilities, subject to validated controls that ensure the prevention of cross-contamination and mix-ups.

Mr. Mehul Shah led a delegation from IDMA for the Industry Interaction with Hon'ble Minister for Commerce & Industry on 14th August 2025 at Vanijya Bhawan (Delhi). He mentioned that the issue of whether pharmaceutical companies should be permitted to manufacture nutraceutical products in their existing facilities was raised. The argument presented was that there is substantial spare capacity in many pharma units, which could be productively utilized for nutraceutical production. While the DCGI has been against allowing this overlap, it was emphasized that such permission should be granted provided nutraceuticals are manufactured to pharmaceutical standards. The DCGI responded positively, stating that he has no objection if the same standards of raw material quality, finished product testing, cleaning and changeover procedures are maintained. He further indicated that a protocol or SOP could be developed to ensure compliance. This suggestion was well appreciated and if implemented, it would allow the industry to optimize capacity utilization and expand into the growing nutraceutical segment. IDMA's representation on this issue received recognition during the discussions.

**NSF – IDMA MoU – Courtesy Nutraceutical Committee**

NSF International approached Dr. R. K. Sanghavi with keen interest to associate with IDMA after attending the Symposium: "Is Indian Nutraceutical Industry Destined to Miss INR 1 Lakh Crore Bus for 2030?" on 9th May 2025 in Mumbai organized by the Nutraceutical Committee. NSF highlighted challenges related to certifications of Nutraceutical facilities and expressed willingness to explore how mutual collaboration could help assure that quality nutraceutical products are available and appropriately recognized by regulators and consumers. NSF conveyed to Dr. R. K. Sanghavi that they are prepared to engage in this dialogue and are seeking an understanding on certification

mechanisms following which a consensus for executing the same was taken at a meeting of the Nutraceutical Committee at the IDMA office on 6th August 2025.

A Memorandum of Understanding (MoU) between IDMA and NSF International was formally signed in New Delhi on 22nd September 2025 at Hotel Le Méridien by Mr. Pedro Sancha, CEO & President, NSF International and Dr. George Patani, Senior Vice President, IDMA to promote cGMP certification of facilities and products in the nutraceutical sector. This collaboration marks an important step towards strengthening quality assurance and building regulatory confidence in the Nutraceutical industry. Through this initiative, IDMA and NSF aim to enhance the credibility and reliability of Nutraceutical products, including the validation of product claims areas that have historically been subjects of regulatory concern and a key reason for discussions around bringing this sector under CDSCO oversight.

**FDC & New Dosage Forms & Softgel DT**

Dr. R. K. Sanghavi highlighted concerns over the inclusion of a commonly prescribed Fixed Dose Combination (FDC) Glimepiride with Metformin 500 IR on the list of FDCs slated for withdrawal as of April 2025. Given the routine use of this combination, the listing of this FDC is surprising and has caused confusion. He requested the Medical Committee to assess the situation and engage with the authorities to seek clarification.

Dr. R. K. Sanghavi also to another critical issue which was the recent move to classify enteric-coated tablets as a new drug dosage form, which could mandate clinical trials and bioequivalence studies even for well-established formulations. This change could impose a significant burden on manufacturers and he has requested Dr. Vinay to prepare a strong industry response to contest this classification.

Dr. R. K. Sanghavi addressed the ongoing challenges related to NSQ (Not of Standard Quality) classifications, particularly affecting soft gelatin capsules. He pointed out that the reduction in Disintegration Time Evaluation (DTE) limits appear to be arbitrary and not aligned with global norms. This has led to an increased number of quality failures. He emphasized the need to gather relevant data and submit a formal representation to regulators to correct this issue.

## REPORT OF PRICING / CONSUMER AFFAIRS COMMITTEE

Dr. Amit Rangnekar, Chairman, Pricing / Consumer Affairs Committee of IDMA nominated Mr. C V Venkataraman as Vice Chairman for the year 2025 – 2026 at the first meeting of the Committee Chairpersons with the National President.

**Provisions of Para 24 of DPCO 2013 relating to carrying in to effect the price fixed or revised by the Government its display and proof thereof**

Dr. Amit Rangnekar mentioned that Smt. Anupriya Patel, Hon'ble Union Minister of State for Chemicals and Fertilizers replied that the dashboard of the integrated Pharmaceutical Database Management system 2.0 displays the effective ceiling prices of 926 formulations and retail prices of 3046 formulations. The data is updated from time to time for the information of all the stakeholders.

Dr. Amit Rangnekar said that NPPA's Pharma Sahi Daam (PSD) displays the brand name, composition, ceiling price and MRP of drugs. At present PSD displays MRP of about 97,400 formulations (Scheduled as well as Non-scheduled) and ceiling prices of Scheduled formulations fixed/revised by NPPA from time to time. He said that despite manufacturers not dealing directly with retailers, the manufacturers are solely held responsible for overcharging even when a single strip is sold at a price above the ceiling. Manufacturers inform the supply chain (C&F agents, wholesalers) of price revisions but have no control over retailers. Yet, they continue to face Show Cause Notices, Demand Notices and recovery actions, causing undue pressure.

IDMA requested that once Form II & V are filed, NPPA should update the PSD. Since retailers access this data, holding only manufacturers accountable should be reconsidered, with suitable amendments to the DPCO.

Dr. Amit Rangnekar suggested that for batches already declared in Form II and Form V on the IPDMS portal, submission of such details should be deemed as compliance, and these batches should not be questioned. Additionally, he mentioned that if the Sahi Daam app is updated to reflect the revised MRPs, the burden of compliance on manufacturers could be minimized, limiting the responsibility to ensuring submission of price intimation forms.

**IDMA Representation - Request for reconsideration of Ceiling Prices allowing 5 decimal points for low priced drugs – NPPA Notification Nos. S.O 1487 (E) & 1489 (E)**

Dr. Amit Rangnekar referred to the recent Gazette notifications on ceiling prices (CP), indicating a WPI of 1.74028%. He said that though there have been significant cost escalations over last 2 years, still the manufacturers of these low-priced essential drugs have not at all been benefited. It is very much essential that the manufacturers of these low-priced drugs should be passed on some benefit within the framework of DPCO 2013 provisions, to ensure continuous availability of these low-priced essential formulations. Prior to 2019, the NPPA adhered to a policy of employing five decimal points in determining ceiling prices for products.

IDMA has requested NPPA to revise Ceiling Prices using five decimal places to support continued supply of low-priced essential medicines and sent a Representation on 28th April 2025 to the Chairman, The National Pharmaceutical Pricing Authority of India (NPPA) with Reference

Gazette notifications: S.O. No. 1587(E) & 1589(E) dated 27.03.2025. wherein Ceiling prices (CP) of Scheduled Formulations were notified giving effect to the WPI of 1.74028%.

Dr. Amit Rangnekar informed the members that the Office of the Economic Adviser, Ministry of Commerce & Industry, has released the Wholesale Price Index (WPI) data for April 2025 (Base Year: 2011–12) with the all-India annual inflation rate recorded at 0.85% (provisional) compared to April 2024. In the category of "Pharmaceuticals, Medicinal Chemical and Botanical Products" the cumulative inflation for Active Pharmaceutical Ingredients (APIs) in 2025 stands at 1.96%, indicating a moderate upward trend in input costs for the pharmaceutical sector.

**Restricted the use of Chlorpheniramine Maleate + Phenylephrine Hydrochloride in children below four years**

Dr. Amit Rangnekar said that the Central Government, under Section 26A of the Drugs and Cosmetics Act, has restricted the use of Chlorpheniramine Maleate + Phenylephrine Hydrochloride in children below four years, mandating a warning on all labels, inserts, and promotional materials. While manufacturers will comply, he raised a key concern about pediatric drops primarily intended for children aged 1–4 years questioning whether this effectively means their withdrawal from the market and seeking clarity on how to proceed. Later there were several deliberations on this subject. It was decided to send a Representation to CDSCO and DTAB seeking guidance and clarification.

**Revising the Guidelines for Export for New and Unapproved Drugs**

Dr. Amit Rangnekar informed the members about the public notice issued by the Government revising the guidelines for export for new and unapproved drugs. IDMA had sent a representation in April 2025 in which IDMA has mentioned that for unapproved/banned APIs and NDPS drugs, regulatory simplifications are necessary to avoid duplication and facilitate exports.

APIs that are not approved by any National Regulatory Authority (NRA) face practical difficulties in furnishing approval documentation, particularly when such regulatory status can already be independently verified by CDSCO through globally available public sources. In this context, IDMA has sought an exemption from the requirement of submitting importing NRA approvals for such APIs.

Similarly, in the case of NDPS drugs, the additional requirement of obtaining a CDSCO export NOC—over and above the stringent, purchase order–specific and quantity-specific scrutiny already carried out by the Central Bureau of Narcotics (CBN), Gwalior, under the NDPS Rules—results in duplication of regulatory processes between two central authorities. It was therefore requested that the existing CBN approval mechanism be deemed sufficient, in order to avoid procedural delays and to align with the Government's 'Ease of Doing Business' initiative.

Dr. Amit Rangnekar raised concerns about export guidelines for unapproved drugs and NDPS drugs, highlighting issues with batch sizes and multiple orders. Dr. Viranchi Shah offered to help

rectify the problem with NOC conditions that restrict supplying from one batch to multiple orders. Regarding NDPS drugs, Dr. Viranchi Shah explained that NOC is required first before obtaining NDPS clearance, as NDPS authorities act based on the CDSCO document.

**Circular dated 22nd July 2025 on the EPA Funding Statement**

Dr. Amit Rangnekar referred to the Circular dated 22nd July 2025 on the EPA funding statement, since its implications are unclear. He read out the key lines, which state that no manufacturer can increase the price of an unscheduled drug by more than 10% in a 12-month period, which is already the law under DPCO and is being complied with by all manufacturers. However, the circular further directs that all manufacturers must align the prices of non-scheduled formulations launched under different brands as per the provisions of Para 20 of DPCO 2030, ensuring that the difference in MRP is not more than 10%. He mentioned that the Circular is not clear and indicated that we should wait for more clarity. He further emphasized the need for caution, given that both marketers and management could face serious implications if these ambiguities are not addressed.

**Rationalization of GST slabs**

Dr. Amit Rangnekar informed the members about the recent announcement made by Hon'ble Prime Minister Shri Narendra Modi regarding rationalization of GST slabs. He shared the perspective discussed in the subcommittee meeting. The current GST slabs of 28%, 18%, 12%, and 5% are proposed to be consolidated into two rates 18% and 5%. Under this framework, the 12% slab, which covers a large share of pharmaceutical products, is expected to move down to 5%. He pointed out that while 18% GST currently generates about 65% of overall Government revenue, 28% (the so-called sin tax) contributes around 11%, 12% contributes only 5% and 5% contributes 7%. Thus, the Government is keen that almost all items under 12% move into the 5% slab, with medicines likely to be shifted accordingly.

He explained that while this would reduce medicine prices and benefit patients, there are practical challenges for the industry. The most pressing issue concerns market stocks already manufactured and distributed at 12% GST before the notification comes into effect. Unless a sunset clause of 3–6 months is granted for liquidation of such stocks, companies will face compliance difficulties. Without this provision, questions arise on whether stocks will have to be recalled, re-stickered, or written off, with the industry bearing a probable hit of around 6.54% on revenue-neutral MRP differences. Another major concern is the inverted duty structure, where inputs such as APIs attract 18% GST, while finished formulations will fall under 5% GST. This mismatch will create cash flow complications and will especially affect contract manufacturers unless GST on APIs is also reduced in line with formulations. Dr. Amit Rangnekar cautioned that without a sunset clause, the industry may face a surge of notices for non-compliance.

He suggested that IDMA should strongly represent to the authorities that at least 6–12 months transition be provided, similar to the relief given during the initial GST implementation in 2017. At

that time, companies were given 15 days to intimate price changes to NPPA and 90 days to clear old stocks through relabelling or withdrawal. On this precedent, IDMA could request a minimum of 180 days.

Dr. Amit Rangnekar emphasized the need for careful examination of the nuances and implications of this transition and recommended close coordination with Mr. B G Barve, Chairman, Taxation Committee of IDMA to frame a comprehensive representation to safeguard industry interests while ensuring smooth implementation.

**Representation on GSR 757 (E) dt.16.10.2025 wrt Expansion of Schedule H2**

Mr. S M Mudda, Chairman Regulatory Affairs Committee, IDMA briefed the members that IDMA has submitted a representation the proposed expansion of Schedule H2, which mandates the use of QR codes/barcodes on 300 specified drugs. He explained that, while the barcoding system has been partially implemented as per the notification, there is currently no mechanism to verify the authenticity of these codes. There is no central database or repository where codes are stored, tracked or decommissioned upon dispensing. As a result, the end-to-end traceability mechanism remains incomplete.

IDMA highlighted this gap and emphasized that, although awareness creation and affixing of codes on branded packs have progressed well, the system must now be taken to its logical conclusion. A Government-managed central hub must be established to enable verification, detection of duplicates, and automatic alerts across the regulatory network.

IDMA further recommended that only after such a system is fully implemented should any additional categories including life-saving and sensitive drugs be considered for inclusion under Schedule H2. Until then, expansion to these categories should be kept in abeyance.

Dr. Amit Rangnekar informed the members that, although the QR/barcode system has been implemented on the top 300 drugs for almost three years, awareness and public engagement remain extremely low. He highlighted that despite the significant effort and investment made by the industry estimated at ₹3–4 crore in total and 30–35 paise per pack only three queries have been received since implementation began. Of these three queries, two were related to practical difficulties (poor lighting for scanning and inability to scan due to not having an Android phone). Only one query pertained to authentication, which clearly demonstrates that the core objective of the system public verification and detection of falsified medicines is not being achieved. He stressed that the government must sensitize the public and strengthen the ecosystem, as the current system has not delivered the intended outcomes despite industry-wide compliance and significant expenditure.

Dr. Amit Rangnekar further noted that the authorities are now considering extending the requirement to additional categories such as Nutraceuticals, NDPS, cancer drugs, vaccines,

antimicrobials and more. A new circular has also been issued mandating that from 1st March 2026, all excipients must be included in the authentication measures for the Top 300 drugs which carry QR codes. He pointed out that this circular was embedded within multiple other notifications, making it difficult for many stakeholders to track and understand its implications. As a result, excipients would now need to be included as part of the "top 300 drugs" QR Code framework with all its other requirements.

**IPDMS – feedback of the industry on the functionality of IPDMS**

IDMA submitted its response with regards to a GSR on 13th November 2025 highlighting several operational challenges faced while using the system. One major issue is that the portal logs users out frequently sometimes within 5–10 minutes of inactivity which becomes problematic when filing large volumes of data for hundreds of products. IDMA has requested that this functionality be improved.

He further noted concerns related to **Form–II**, where GST rates must be entered repeatedly and fields such as WPI and selling price are not updated in the system, increasing the risk of incorrect calculations. Additionally, the requirement to manually enter the manufacturing date every time is cumbersome; for example, after entering "September 2025" once, the system should ideally retain the value instead of requiring it to be re-entered.

Another key issue raised pertains to the lack of consolidated reports. Previously, the system allowed users to generate summary reports, but the current version does not. IDMA has requested restoration of the functionality to enable users to view consolidated submissions such as how many times Form–V or other forms have been submitted for at least the past three years. He stated that these points collectively form the essence of IDMA's submission to NPPA.

**NPPA organized an online workshop/training session on 20th November 2025**

Dr. Amit Rangnekar informed the members that NPPA organized an online workshop and training session on 20th November 2025 to support companies in onboarding and effectively using the system. This session provided a detailed walkthrough of the platform, including its key features, the registration process and step-by-step guidance on submitting various forms.

## REPORT OF PUBLICATIONS COMMITTEE

Dr. George A. Patani, Chairman of the Publication Committee of IDMA, proudly announced his Publication Committee comprising of Dr. A. Patani, D.Sc. (Germany), as Founder Editor, Dr. Gopakumar G. Nair as Editor and Dr. Nagaraj Rao would continue as Vice Chairman and Associate Editor. There were two new additions to the Publication Committee with Dr. Srividya Ravi being appointed as Consulting Editor and Mr. Ved Prakash Pandey as Technical Editor. Dr. George A. Patani appreciated the dedicated efforts of the IDMA Secretariat in ensuring

the timely publication of the IDMA Bulletin, Indian Drugs & IDMA Annual Publication, year after year.

**Meetings of the IDMA Publication Committee**

IDMA Publication Committee under the chairmanship of Dr. George Patani had five meetings during the year on 12th February, 20th March, 1st April, 23rd April and 13th December 2025 to discuss various issues with regards to the IDMA's publications, subscriptions, distribution, etc.

**IDMA Bulletin – Editorials & Advertisements**

The IDMA Bulletin has enhanced the value of its publications through contributions from Guest Editors and paid Editorials on the latest innovative happenings in the Pharmaceutical Industry. The Advertisements in the IDMA Bulletin has also increased and Dr. George A. Patani expressed his sincere appreciation to Mr. Bharat N. Shah, National President and Mr. Mehul Shah, Vice President, Western Region, for their efforts in boosting advertisements and thereby increasing revenue for the Publication as well as IDMA.

**APEX Subscription Agency**

IDMA evaluated the feasibility of engaging a private agency to facilitate distribution as well as onboarding of new subscribers. Pursuant to this, Dr. George Patani held discussions with Apex Subscription Agency and it was agreed to commence fresh subscriptions exclusively for Indian Drugs as a way forward. The proposal was approved with an initial target of five new subscriptions. As of date, the Agency has successfully enrolled 30 new subscriptions for Indian Drugs.

**Dr. S G Deshpande retired as Consulting Editor**

Dr. S. G. Deshpande, Consulting Editor, expressed his desire to retire from his role as Consulting Editor of the Indian Drugs publication owing to age-related reasons, after successfully rendering many years of dedicated and diligent service. Dr. Gopakumar G. Nair and Dr. George A. Patani placed on record their sincere appreciation and thanked him profusely for his exemplary service to the Indian Drugs publication and IDMA. IDMA expressed its gratitude for his valuable and longstanding contributions and accepted his request to retire.

IDMA appointed Dr. Srividya Ravi as the new Consulting Editor. Dr. George A. Patani sincerely thanked Dr. Gopakumar G. Nair for recommending and facilitating this smooth transition.

**Indian Drugs**

The monthly scientific and research publication, Indian Drugs continued to be published in both hard copy and digital formats during the year. IDMA expresses its sincere gratitude to the Editor, Dr. Gopakumar G. Nair, Associate Editors - Dr. Nagaraj Rao and Dr. George A. Patani; Consulting

Editors - Dr. S. G. Deshpande and Dr. Srividya Ravi and Technical Editor, Mr. Ved Prakash Pandey as well as the Members of the Editorial Board, the Editorial Advisory Board and all Reviewers for their ongoing continued support.

Indian Drugs has been assigned an online ISSN number for its publication. To secure the online ISSN, the necessary modifications were made to the website and the constitution of the Editorial Board members in accordance with ISSN requirements. The journal is revising and adding the policies such as Presence of Ethics Statements, Policy for retractions and corrections to meet the international standard. Indian Drugs is currently indexed by over 45 international abstracting databases, including Scopus, EMBASE, International Pharmaceuticals Abstracts, EBSCO and Index Copernicus. In the current year, five additional databases EuroPub, R Discovery, PSIref, ivySCI, and AskBisht have been included in the list of indexing databases of INDIAN DRUGS. The necessary changes to the website are also in process for indexing in NLM-MEDLINE, Clarivate/ Web and Chemical Abstracts.

The journal received approximately 1112 manuscripts in 2025 and reviewed 945 of them within the same year. All articles were screened by plagiarism software – Turnitin, prior to publication.

In total, 114 articles were assigned to DOIs and their details were uploaded on Crossref.

**IDMA 63rd Annual Day Publication**

IDMA released the 63rd Annual Day Publication on Saturday, 8th February 2025 at Hotel Taj Mahal Palace, Mumbai during the Annual Day Celebrations at the auspicious hands of the Chief Guest Shri Piyush Goyal, Hon'ble Minister for Commerce and Industry.

The 63rd Annual Publication contained the following:

- Report of NMPA Approvals (2023-2024) for Finished Products by Indian Companies in China by Pharmacodia Global – SaSPinjara
- Export and Import of Bulk Drugs and Intermediates (All Countries) during the Year 2023-24 and from April 2024 to November 2024
- Export and Import of Drug Formulations and Biologicals (All Countries) during the Year 2023-24 and from April 2024 to November 2024
- New Drugs approved for Marketing by Drugs Controller General (I) during the period from January 1961 to 26th December 2024
- Approved BA / BE Centres in India
- Health Statistics of India

# REPORT OF QUALITY MANAGEMENT & TECHNICAL COMMITTEE

### Meeting to discuss issues related to Registration of Clinical Research Organization (CRO)

CDSCO convened a virtual meeting (via Webex) on 27th March 2025 to discuss issues related to the registration of Clinical Research Organizations (CROs) on the SUGAM Portal. The meeting was chaired by Mr. R. Chandrashekhar, Joint Drugs Controller of India (Jt. DCI) and Mr. Navneet Prasad Singh, Deputy Drugs Controller of India (Dy. DCI). Dr. Vinay Nayak, Chairman, Quality Management & Technical Committee, IDMA expressed serious concerns regarding a recent case involving a manufacturer, previously regarded as reputable, which was found to have significant data integrity lapses in test results. More than 238 data changes were identified and subsequently rendered invalid, raising critical concerns about documentation standards in laboratories, particularly those involved in studies with human volunteers. He further mentioned that three to four additional manufacturers have come under similar scrutiny in the past six months and that there is a need for collective industry action, including the development of clear guidelines and defined timelines to strengthen documentation and data integrity practices. Dr. Nayak also mentioned it is observed that current inspection processes may not be sufficiently rigorous and stressed the importance of closer collaboration between regulators and industry stakeholders involved in clinical research.

### First Meeting of the IDMA's Quality Management & Technical Committee

The first meeting of IDMA's Quality Management & Technical Committee was held on 19th June 2025 under the chairmanship of Dr. Vinay Nayak. The meeting focused on reviewing the objectives of the technical groups, discussing upcoming initiatives and events and addressing key challenges in quality management. Emphasis was placed on strengthening industry capabilities through targeted training programs, enhanced collaboration, implementation of guidelines and the development of technical resources including bulletins like APA Forum. Plans for the upcoming 24th Pharmaceutical Analyst Convention (PAC) and future periodic committee meetings were also discussed to ensure sustained progress. The key action points emerging from the meeting included the development of Standard templates for risk analysis and documentation to support MSMEs in implementing robust quality systems; the design and delivery of focused training programs on Quality Management Systems (QMS) and GMP compliance; the revival of the IDMA Quality Excellence Awards with inspections proposed to commence from October 2025. He proposed the revival of the Analytical Professionals Association (APA) and its technical bulletin – APA Forum with topics on microbiological practices and pharmaceutical guidelines. He proposed that the committee should organize workshops on quality-related topics. It was also discussed that Contract Research Organizations (CROs) should be encouraged to become IDMA members, enabling them to receive structured support in implementing Good Manufacturing Practices (GMP) and aligning with regulatory expectations.

**Green Pharmacopoeia Initiative – IDMA Nomination and First Meeting**

IDMA nominated Dr. Milind Joshi and Dr. George Patani as IDMA's representatives to the Green Pharmacopoeia Initiative. The first meeting of the Initiative was held on 10th November 2025.

Key suggestions and focus areas discussed during the meeting included:

- Transition from print to digital-only formats for pharmacopoeial publications.
- Reduction in chemical usage during analytical procedures.
- Elimination of animal testing wherever feasible.
- Reduction in the use of Class I solvents.
- Promotion of additional green and sustainable practices across pharmacopoeial standards.

In addition, the issue relating to the mandatory use of virgin plastic in Form-Fill-Seal (FFS) manufacturing was also deliberated during the meeting.

**DCC Sub-Committee Meeting on Guidance Document for Quality of Excipients**

The Drugs Consultative Committee (DCC) has constituted a sub-committee to frame a Guidance Document on Quality of Excipients, in the backdrop of recent quality-related developments. The sub-committee is convened by Dr. A. Ramkishan, Deputy DCGI, with Shri Gahane, Joint Commissioner, FDA Maharashtra, and the Deputy Commissioner, Gujarat FDCA, among the members.

The meeting was hosted by IPEC India at the SciTech Centre. Several IPEC members, including Shri Ajit Singh, Chairman, IPEC India, were present. Dr. A. Ramkishan made a detailed presentation on the draft Guidance Document. Shri Satish Wagh, Chairman, CHEMEXCIL, also attended the meeting.

Key discussion points included:

- Introduction of GMP requirements for excipients.
- Discussion on regulation/licensing of imported excipients, with no immediate proposal indicated.
- Need for enhanced oversight of contract testing laboratories.
- ONDLS registration and additional control measures for high-risk excipients, including identified solvents.
- Possible future creation of an excipient database, similar to the Inactive Ingredient Database (IID).

The draft Guidance Document is largely based on international best practices, particularly IPEC's EXCiPACT, a globally accepted certification standard for pharmaceutical excipient suppliers.

Dr. Milind Joshi represented IDMA at the meeting and emphasized that no additional bureaucratic procedures should be introduced that could adversely impact pharmaceutical manufacturers

## 24th IDMA PHARMACEUTICAL ANALYSTS CONVENTION (PAC) 2025

The 24th Pharmaceutical Analysts' Convention (PAC) 2025 was held successfully on Tuesday, 16th December and Wednesday, 17th December 2025, at Hotel Sahara Star, Mumbai. The theme was "Sustainable Quality Excellence through Regulatory Compliance and Technological Innovation." The 24th PAC 2025 was conducted with great success, attributing this achievement to the effective leadership of the IDMA National President and the guidance of the Technical Committee and the dedicated efforts of the IDMA Secretariat. The Convention witnessed strong participation, with over 300 delegates on Day 1 and more than 250 delegates on Day 2, reflecting sustained interest from industry professionals.

The Convention was graced by Padma Vibhushan Prof. Dr. Man Mohan Sharma, FNA, FRS, Emeritus Professor of Eminence, Institute of Chemical Technology (ICT), Mumbai, as the Chief Guest and Keynote Speaker. Dr. Vivekanandan Kalaiselvan, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission (IPC) and Dr. Girish Kapur, Senior Vice President – India Site Operations & USP India-Site Head, United States Pharmacopeia were the Guests of Honour. During the Convention, Prof. Dr. M. M. Sharma was conferred the prestigious IDMA Vigyan Ratna Award in recognition of his outstanding contribution to science and industry. In his keynote address, Prof. Sharma traced the evolution of the API industry, reflected on its formative years, and highlighted critical measures required to ensure long-term growth, innovation, and self-reliance in API manufacturing. The address was highly appreciated by the delegates. The Convention was further enriched by the address of Dr. Vivekanandan Kalaiselvan, who shared key initiatives undertaken by the Indian Pharmacopoeia Commission, which were well received by the participants.

Two impactful panel discussions were also conducted: "Embedding Quality with AI: Redefining Standards of Excellence," moderated by Mr. Mehul Shah, and "Sustainability in GMP: Regulatory Expectations & Industry Efforts," moderated by Mr. S. M. Mudda. Both sessions generated active interaction and were widely appreciated for their relevance and depth. PAC 2025 featured technical sessions and presentations by 14 eminent industry experts, including focused discussions on Supply Chain Resilience & Security and Quality Culture and Skill Enhancement Techniques. On Day 2, the convention had sessions on allied themes, adding a broader perspective to the Convention. Dr. Girish Kapur address on USP Standards: Shaping the Future of Medicines and Improving Public Health. A session on Holistic Health was delivered by Dr. Mickey Mehta, while Mr. Yashasvi Yadav, IPS, Additional Commissioner, Cyber Crime, Mumbai Police, addressed participants on Cyber Crime Awareness. Both sessions were well received and added significant value beyond the core technical discussions. Dr. George A Patani, Sr. Vice President – IDMA delivered the Valedictory Address and Dr. Milind Joshi, Vice Chairman efficiently & successfully facilitated the event on both days.

IDMA 24th PAC Awards Winners

1. IDMA Vigyan Ratna Award - Padma Vibhushan Prof. Dr. Man Mohan Sharma
2. Prof Dr R T Sane Outstanding Pharmaceutical Analyst Award - Mr. A V Jayakumar, President - Quality, Ajanta Pharma Ltd.
3. IDMA Outstanding Young Scientist Award - Mr. Tarachand B. Pisal, Encube Ethicals Pvt. Ltd.
4. IDMA Eminent Scientist Award - Dr. Damodharan Muniyandi, Chief Quality Officer, Sai Life Sciences Ltd.
5. IDMA Lifetime Achievement Award - Shri S W Deshpande, Former Joint Commissioner, FDA, Maharashtra & Proprietor, PHARMALEX

Dr. Vinay Nayak thanked the IDMA National President, Quality Management & Technical Committee Members and IDMA Secretariat for their strong support and teamwork. He specially acknowledged Mr. Mehul Shah for mobilizing sponsorships and supporting registrations and reiterated that PAC 2025 stands as a flagship and landmark event for IDMA.

## REPORT OF REGULATORY AFFAIRS COMMITTEE

Mr. S M Mudda, Chairman of the Regulatory Affairs Committee of IDMA mentioned that the Regulatory Affairs Committee had a very vibrant and fruitful year 2025 wherein IDMA was able to respond to various queries of the Ministry as well as the Government and also address the issues faced by the Indian Pharmaceutical Industry by appropriate Representations & Suggestions. Mr. S M Mudda was ably supported by Mr. S W Deshpande, Vice Chairman and his Committee Members.

### IDMA – CDSCO Workshops as per the Revised Schedule M

IDMA was the only industry association authorised by CDSCO to conduct PAN-India training programmes for both members and non-members of the pharmaceutical industry, aimed at facilitating industry preparedness and compliance with the Government's expectations under the Revised Schedule M.

### Fifth Workshop on Revised Schedule M on Saturday, January 18, 2025 at Visakhapatnam Workshop on Good Practices In Production As Per The Revised Schedule M

The fifth workshop in the IDMA – CDSCO series on the Revised Schedule M was successfully conducted on Saturday, January 18th, 2025 in Visakhapatnam. The one-day workshop on Good Practices in Production, aligned with the revised regulatory requirements under the Revised Schedule M, received an overwhelming response, with over 300 participants attending in person and approximately 2,000 participants joining online. The workshop featured a distinguished panel of expert speakers who addressed key aspects of pharmaceutical manufacturing and compliances. The technical sessions were led by Mr. Manish Bhatkar, Mr. Subramanyam Maddala, Mr. Mahesh Vyas

and Mr. Biju Nair, who shared practical insights, regulatory expectations and industry best practices. The interactive discussions were highly engaging and facilitated meaningful knowledge exchange among participants. Overall, the workshop was a resounding success, reinforcing regulatory awareness, promoting good manufacturing practices and supporting industry preparedness for effective implementation of the Revised Schedule M.

**Sixth Workshop on Revised Schedule M on Saturday, 29th March 2025 at Kolkata**

**Workshop on Good Practices in Quality Control as Per the Revised Schedule M on Saturday, 29th March 2025 at Kolkata**

The CDSCO workshop held in Kolkata on 14th April marked the successful culmination of a significant phase of engagement between the industry and regulators. The programme witnessed over 290 participants attending in person along with more than 2,400 participants joining virtually, including industry delegates, regulatory officials and distinguished dignitaries.

In the Technical Session 1, Mr S.M.Mudda, Chairman, Regulatory Affairs Committee, IDMA & MD, Misom Labs Ltd, Malta spoke on **Pharmaceutical System : The Philosophy behind the GMPs**. In his deliberation he explained how Revised Schedule M embraces a more holistic and proactive approach to quality management encompassing the entire product life cycle, thereby enhancing Consumer Trust and bolstering the Brand India Reputation. This was followed by a presentation on **Quality Risk Management** by Dr. Milind Joshi, Vice Chairman, Quality Management & Technical Committee, IDMA & Professor of Practice at Ramnarain Ruia Autonomous College, Mumbai. Dr. Joshi explained the key objectives of Quality Risk Management (QRM) which includes Identifying Potential Risks, Reducing Risks to acceptable levels and implementation of continuous monitoring and improvement.

IDMA thanked Dr. Eswara Reddy and his team at CDSCO, along with Dr. Rajeev Raghuvanshi, DCG(I), for their continued efforts in upgrading Indian pharmaceutical facilities in line with WHO-GMP standards. All six workshops held at Bengaluru, Baddi, Daman, Ahmedabad, Visakhapatnam, and Kolkata were highly successful and effectively trained both industry participants and CDSCO/State FDA officials. Mr. S M Mudda applauded Dr. Eswara Reddy, the CDSCO and State FDA Officials, Mr. Daara B Patel & the IDMA Secretariat, Speakers and participants for their active involvement in making these six workshops a huge success.

**IDMA Suggestions on Draft Notification GSR 10(E) dated 04.01.2025 with reference to Revised Schedule M**

IDMA, in coordination with other Industry Associations, submitted a Representation in response to the Draft Notification GSR 10( E) dated 04.01.2025 with reference to Revised Schedule M, which resulted in the grant of a one-year extension. This extension, however, was made conditional upon manufacturers submitting a formal undertaking to the Government, detailing their respective

upgradation plans. In its submission, IDMA requested that such applications be permitted to be filed with both the State Licensing Authorities (SLAs) and the CDSCO. IDMA has also advised manufacturers to prepare and submit their upgradation plans well in advance, as those who comply within the stipulated timeline will be eligible for consideration under the extended period.

**Meeting of Secretary (Health) with Industry**

Ms. Punya Salila Srivastava, Secretary (Health), chaired a meeting with industry representatives on 31st January 2025. She was supported by Mr. Rajiv Wadhawan, Joint Secretary & Adviser (Cost), and Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI). Mr. S.M Mudda represented IDMA for the meeting. During the meeting, IDMA made a detailed presentation highlighting several key regulatory issues, including the uniform implementation of the Revised Schedule M, the non-enforcement of guidelines for handling Not of Standard Quality (NSQ) cases under Section 33(P) and the requirement of Form 29 for the manufacture of products intended for examination, testing or analysis. Additional matters discussed included the compounding of select offences under the Jan Vishwas (Amendment of Provisions) Act, 2023, the need for improvements in regulatory approval timelines, clarifications related to drug exports and the issuance of No Objection Certificates (NOCs), and the manufacture of nutraceutical products in shared facilities. Ms. Punya Salila Srivastava acknowledged and appreciated IDMA's presentation, noting the relevance of the issues raised and the constructive inputs provided by the Association.

**DPIIT Meetings with regard to Reducing Compliance Burden**

The Department for Promotion of Industry and Internal Trade (DPIIT) held two meetings on 20th December 2024 and 20th January 2025 to discuss initiatives aimed at reducing the compliance burden and sought inputs from industry stakeholders. Pursuant to these discussions, IDMA submitted its recommendations on 30th January 2025 to the Deputy Secretary, DPIIT, addressing key matters including decriminalisation of offences, compounding of offences under the Jan Vishwas (Amendment of Provisions) Act, 2023, pricing reforms, implementation of the Revised Schedule M, and the proposal to treat APIs and intermediates as a single regulatory category. Further, based on the suggestions put forward by Mr. Devesh Malladi, IDMA submitted an additional representation on 6th February 2025 to DPIIT, recommending voluntary filing of returns for common chemicals, reagents, catalysts, and solvents, particularly in relation to NDPS-related compliance issues.

**Virtual Meeting on the extension of implementation of the revised schedule-M and demo for filing the application seeking extension on ONDLS portal**

The Central Drugs Standard Control Organization (CDSCO) convened a virtual meeting on 14th February 2025 to deliberate on the extension of timelines for implementation of the Revised Schedule M and to provide a demonstration on the process for filing applications through the ONDLS portal. The meeting was chaired by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI) and supported by Mr. Ranga Chandrashekhar, Joint Drugs Controller of India (Joint

DCI). During the discussion, Mr. S. M. Mudda expressed the industry concerns regarding the requirement for implementation of air-lock systems in existing manufacturing facilities, highlighting that retrofitting such infrastructure poses significant practical and technical challenges and in many cases may not be feasible.

**Expert Working Group under the MSME initiative**

IDMA published an announcement in the IDMA Bulletin on 14th April 2025 inviting applications for the Expert Working Group under the MSME initiative. MSME units were encouraged to submit their requests for support. This initiative was specifically designed to assist MSMEs undertaking Gap Analysis, who were required to submit their applications to the DCGI office within 90 days, along with the prescribed action plans. To facilitate this process, IDMA arranged a no-cost preliminary review of applications by an expert committee. Further, as guided by the National President, MSMEs were advised that they may directly engage expert advisors, based on their specific and individual compliance requirements.

**WHO SEARN proposed convergence mechanism on Marketing Authorization - Preliminary informal consultation with Industry**

The World Health Organization (WHO), Southeast Asian Regulatory Network (SEARN), with the support of the International Cell of CDSCO, organised a preliminary informal consultation with industry stakeholders on 21st April 2025 to discuss SEARN's proposed convergence mechanism for marketing authorisation. SEARN is a voluntary network of National Regulatory Authorities (NRAs) representing 11 countries in the Southeast Asia region. This industry consultation was proposed during the SEARN Working Group 2 (WG2) meeting held on 13th February 2025, where members underscored the importance of engaging industry stakeholders in advance of the SEARN Assembly scheduled for July 2025. Mr. S M Mudda informed that the objective of the consultation was to solicit industry feedback on the draft convergence mechanism being developed by WG2 (Medicines and Vaccines) and WG5 (Medical Devices), which are mandated to identify priority products for regional regulatory convergence and alignment. Representatives from India, Bangladesh, Bhutan, Indonesia, Maldives, Nepal, Sri Lanka, Thailand, Timor-Leste, and Switzerland participated in the meeting. During the session, the SEARN Secretariat provided an overview of the network and presented the draft proposal for discussion. Industry participants shared their expectations, specific operational needs, and constructive suggestions to support the development of an effective and pragmatic convergence mechanism.

**Manufacturing and Marketing of Unapproved FDCs**

The Central Drugs Standard Control Organization (CDSCO) issued a letter dated 11th April 2025, advising all State Drug Controllers to ensure that the Fixed Dose Combinations (FDCs) listed in the annexure to the letter, as well as any other unapproved FDCs, are not permitted for manufacture, sale, or distribution in the country. In this context, IDMA submitted a Representation

to the Drugs Controller General of India (DCGI) on 30th April 2025, requesting a revision of the list of unapproved drugs by deleting the products listed at Serial No. 1 and Serial No. 29, as these combinations have already been approved by CDSCO. With reference to the circular dated 11th April 2025, several IDMA member companies highlighted factual discrepancies in the annexure listing the banned drugs. Specifically, the products mentioned at Serial No. 1 and Serial No. 29 appeared to have been previously approved by CDSCO, as evidenced in the respective DCGI-approved FDC lists.

Mr. S. M. Mudda explained that at Serial No. 1, the circular lists the combination of Mirabegron 25 mg and Solifenacin Succinate 5 mg as banned. However, this combination is included at Serial No. 24 of the CDSCO-approved FDC list for the period January 2022 to August 2022, covering Mirabegron (25 mg/50 mg as extended-release tablets) and Solifenacin Succinate (5 mg as immediate-release tablets). Similarly, at Serial No. 29, the combination of Glimepiride 1 mg and Metformin HCl 500 mg is indicated as banned, whereas the CDSCO-approved FDC list up to December 2019 clearly includes this combination at Serial Nos. 355 and 363, in sustained-release tablet formulations. In view of the above, IDMA requested CDSCO to revise the list of unapproved drugs by removing the products mentioned at Serial No. 1 and Serial No. 29, in order to correct the discrepancies and avoid unintended regulatory and commercial implications for compliant manufacturers.

**Representation – Guidance & Advice on 'Reference Products for Conduct of BE Study**

IDMA submitted a Representation on 2nd May 2025, to the Drugs Controller General of India [DCG(I)] seeking guidance and clarification on the selection of "Reference Products for the conduct of Bioequivalence (BE) studies." The Representation referred to the CDSCO Office Notice dated 22nd January 2020 (F. No. 12-32/2019-DC(Pt-Misc-SND)) and the DCG(I) Gazette Notification dated 3rd April 2017, which mandate the submission of bioequivalence study data for oral dosage forms of drugs classified under BCS Class II and IV. While CDSCO has published a list of 139 monotherapy products along with their designated reference products, the list is limited to tablets and capsules and does not include reference products for other oral dosage forms, such as dry syrups, oral suspensions/liquids, or Fixed Dose Combination (FDC) products falling under BCS Class II and IV.

Mr. S. M. Mudda informed members that the 2020 Office Notice had indicated that the reference product list would be expanded as additional information became available. However, no updated or comprehensive list has been issued to date. Furthermore, several reference products included in the existing list—such as Cefpodoxime Proxetil (Serial No. 28: Sandoz and Aurobindo)—are no longer available in the Indian market. Although the notice permits the use of CDSCO-approved Indian products as reference products when innovator products are unavailable, ambiguity persists, particularly with respect to selection criteria for FDCs. In the absence of a complete and updated reference product list, the pharmaceutical industry is facing significant challenges in identifying and

procuring suitable reference products for BE studies. Accordingly, IDMA has requested CDSCO to issue an updated and detailed list of reference products, covering dry syrups, oral suspensions/ liquids, and FDCs, along with clear guidance on acceptable alternative options when designated reference products are not available in the Indian market.

**Ministry of Health and Family Welfare Notification GSR 259 (E), dt 24.4.2025 w.r.t. Compounding of Offences**

The Ministry of Health and Family Welfare has issued G.S.R. 259(E) dated 24th April 2025, notifying the Drugs and Cosmetics (Compounding of Offences) Rules, 2025. These Rules establish a statutory framework for the compounding of specified offences under the Drugs and Cosmetics Act, 1940. Under the notified Rules, individuals and entities engaged in the manufacture, import, sale, or distribution of drugs and cosmetics may apply for compounding of eligible offences as an alternative to prosecution, subject to the prescribed conditions. The notification clearly identifies the competent authorities empowered to compound offences, prescribes the application process, and sets out the terms and conditions for the grant, withdrawal, or revocation of immunity from prosecution. The introduction of these Rules is intended to rationalize regulatory enforcement while providing a structured and efficient mechanism for resolving non-serious violations in a time-bound and transparent manner.

**Webinars to create awareness about Ensuring Pharmaceutical Quality Assurance through Good Manufacturing Practices & RPTUAS Sub-scheme: SIDBI**

The Department of Pharmaceuticals (DoP), Central Drugs Standard Control Organization (CDSCO) and SIDBI, in collaboration with IDMA, organized a series of Six Awareness Webinars on “Ensuring Pharmaceutical Quality Assurance through Good Manufacturing Practices (GMP)” and the RPTUAS Sub-scheme. This initiative was undertaken to sensitize stakeholders across major pharmaceutical clusters in India on regulatory expectations, quality assurance and available support mechanisms. The sectors were Tamil Nadu, Puducherry & Kerala State Board, Karnataka State Board, Telangana State Board, Gujarat State Board (Ahmedabad & Vadodara) and Baddi Cluster. The Key highlights of the webinars, along with two principal presentations were published in the IDMA Bulletin for the benefit of the readers.

**IDMA’s Representation on proposed measures relating to NSQ products and suspension of Licenses**

CDSCO organized an virtual meeting on NSQs on 17th May 2025, Mr. S M Mudda attended on behalf of IDMA to discuss the proposal for suspension of product permission declared Not of Standard Quality Drug by a Government Analyst of a Government Testing Laboratory. The same was deliberated during the 92nd DTAB meeting held on 24.04.2025. IDMA submitted a Representation on 1st July 2025 to the DCGI.

**IDMA Representation to CDSCO Circular (BCS Classification) letter dt. 11.9.2025 with regard to Withdrawal/Cancellation of product permission for not implementing dated 03.04.2017**

IDMA submitted a detailed Representation to the Department of Pharmaceuticals in response to the circular dated 11th September 2025, which directs State Licensing Authorities (SLAs) to cancel or withdraw product permissions granted without Bioequivalence (BE) data for BCS Class II and IV oral solid dosage forms. The circular refers to the provisions of Rules 74(q), 74B(8), 76(10), 78(r), and 78A(9), as amended vide GSR 327(E) dated 3rd April 2017. He said that the industry has expressed serious concerns regarding the retrospective enforcement of these provisions and the possible actions by SLAs without due consideration of ground realities. The Representation seeks urgent clarifications and guidance on the key aspects such as that it was requested that the BE requirement under GSR 327(E) should not apply to products manufactured solely for export, as these already comply with the importing country's regulatory standards. Directions have been sought to SLAs to not insist on BE studies for such export-only products.

The representation reiterates that GSR 327(E) came into effect prospectively from 5 August 2017, and therefore, the BE requirement should not apply to products licensed prior to that date. This position aligns with established legal principles and Supreme Court judgments holding that laws operate prospectively unless explicitly stated otherwise. In the representation the reference was made of the international precedents USFDA, EMA, and WHO where BE requirements are applied prospectively and risk-based, with provisions for biowaivers under justified conditions. It was emphasized that none of these regulators cancelled existing product approvals retrospectively. IDMA highlighted that in India absence of Reference Listed Drugs (RLDs), post-manufacturing variability, and capacity constraints make mandatory BE testing impractical. Such a blanket requirement, particularly for MSMEs, could disrupt supply continuity without tangible gains in patient safety. He said that we proposed that a phased approach, initially covering BCS II and IV drugs in the National List of Essential Medicines (NLEM) or those with known bioavailability risks, while providing waivers for long-established products (10 years or more) or dissolution-profile-based equivalence where BE studies are not scientifically feasible. It was noted that GSR 327(E) does not provide application formats or procedural guidance for submission of BE or waiver data for older products. Hence, the representation requests that before strict enforcement, the regulatory framework be completed with necessary provisions, forms, and waiver mechanisms in line with WHO and EMA models.

Mr. S M Mudda mentioned that IDMA emphasized that the industry fully supports the scientific intent of GSR 327(E) but seeks balanced, practical and science-driven implementation. He further said that the industry is willing to engage constructively and has requested a meeting with the Department at the earliest convenience to discuss the matter further.

**Meeting regarding management of quality of critical solvent like Propylene Glycol**

Mr. Bharat Shah, Dr. Viranchi Shah, Mr. S M Mudda and other IDMA representatives had a meeting with the Drugs Controller General of India (DCGI). The meeting followed an earlier virtual

discussion and was aimed at reviewing recent developments, Government expectations and the actions required from industry. IDMA reiterated its clear position on the need for strict and uniform enforcement of the existing regulatory framework, especially in light of the recent unfortunate incident involving non-compliant manufacturers. IDMA emphasized that firms failing to meet licensing, scheduling or product and material testing requirements must face appropriate regulatory action. IDMA has formally requested the DCGI to consider issuing a circular under Rule 33P to ensure uniform interpretation and implementation of requirements across all States.

The DCGI has directed mandatory testing of every batch and every container of key excipients replacing the earlier random-sampling approach and stressed the importance of full traceability, vendor qualification, and verification of materials. It was also proposed that IDMA encourage suppliers to provide smaller pack sizes for critical excipients to avoid bulk purchases and reduce the risk of misuse. The linking of approved vendors directly to product licenses was discussed as an additional safeguard, with non-compliance potentially leading to cancellation of approval. Propylene glycol and similar excipients will remain under close regulatory scrutiny. The Indian Pharmacopoeia Commission (IPC) has amended General Monograph 2.4.13, effective 10th October 2025, mandating testing of all batches of excipients and finished products manufactured thereafter. A general GC method has been published for use after method verification. All legacy stocks of excipients must also be tested, and Drug Inspectors have been advised to check compliance during site visits.

Mr. S M Mudda mentioned that the Government also plans to introduce a digital portal to allow manufacturers to upload Certificates of Analysis (CoAs) for raw materials and finished products, facilitating real-time monitoring and feedback in place of periodic inspections. He added that a draft Representation proposing specific amendments to the rules has been prepared and reviewed by Mr. S. W. Deshpande and Mr. Nilesh Gandhi.

**Representation with regard to Risk-Based clarification on mandatory DEG/EG testing for all Oral Liquid Formulations**

IDMA has submitted a representation regarding the risk-based clarification on mandatory DEG/EG testing for all oral liquid formulations on 10th October 2025. Following the meeting held earlier, manufacturers were advised that all oral liquid products must be tested for the absence of DEG/EG as per the monograph published by the IPC. Mr. S M Mudda informed the members that even during the first meeting which he attended, he had raised this concern directly with the authorities. IDMA has now formally represented that such a blanket requirement is not scientifically justified and should instead be limited only to products containing excipients that are known to pose a risk of DEG/EG contamination.

In the initial discussions, authorities had indicated that they would begin by requiring testing for all products and subsequently review the need for amendments. Mr. S M Mudda emphasized that clear, risk-based clarification is essential from the outset, to avoid unnecessary testing and

operational burden. IDMA has requested an official clarification stating that the mandatory DEG/EG testing requirement should apply only to those formulations that use high-risk excipients with known potential for contamination, and not across all oral liquid products.

**IDMA Representation - Request for Specific Provisions under Revised Schedule M**

IDMA made a representation on 16th October 2025 requesting Specific Provisions under Revised Schedule M. IDMA mentioned that while the industry is fully committed to meeting the enhanced expectations under the revised Schedule M, certain provisions require reconsideration to ensure practical and uniform implementation without diluting the core intent of quality assurance. CDSCO has taken a very serious and proactive view on the implementation of the revised norms and has already initiated inspections based on the detailed compliance checklist issued. However, concerns have been raised that in some instances inspections are being conducted in a mechanical manner, without sufficient consideration for the practical feasibility of certain architectural requirements particularly the provision for dedicated Personnel Airlocks (PAL) and Material Airlocks (MAL) as outlined in Clause 1.65 of Part VIII. Several long-established manufacturing facilities, including those licensed well before the latest revision of Schedule M, were designed and approved under earlier GMP frameworks where dedicated PAL/MAL structures were not mandated. Many such units continue to operate fully in line with international expectations USFDA, MHRA, WHO and other regulators by maintaining validated controls such as air-pressure cascades, controlled air changes, differential pressure monitoring, unidirectional flow patterns and documented gowning and cleaning procedures. Global GMP frameworks, including EU GMP, WHO TRS 1025 Annex 2, and ISPE Risk-MaPP, recognize that contamination control can be effectively ensured through risk-based engineering and procedural measures rather than prescribing a single rigid architectural solution.

Accordingly, IDMA's Representation requests that scientifically justified and validated alternatives should be accepted in lieu of mandatory physical PAL/MAL structures. The suggestion is to retain PAL/MAL as the preferred option, while allowing validated engineering and procedural controls that demonstrably prevent cross-contamination to be considered acceptable. This forms the core of the Representation submitted on 16th October 2025.

Mr. S M Mudda mentioned that the second Representation concerns the restriction on manufacturing food and nutraceutical products within pharmaceutical facilities. The Revised Schedule M now requires exclusive use of premises for drug manufacturing, effectively removing the earlier concession under GSR 431(E) dated 30th June 2005 that permitted certain exemptions for units licensed prior to 11th December 2001. It was clarified that the original intent behind these restrictions was to prevent the manufacture of hazardous or incompatible products such as chemicals or pesticides in facilities handling pharmaceuticals, rather than to prohibit allied categories like nutraceuticals that share comparable dosage forms, process controls, and GMP expectations with drug products. International regulators such as USFDA, EMA, and TGA allow such allied products to be produced in shared facilities, provided there is scientifically justified cleaning validation, documented risk assessment, and stringent GMP controls. In line with this global

practice, IDMA has requested that Nutraceuticals and similar allied products may be permitted to be manufactured in pharmaceutical facilities, subject to validated controls that ensure prevention of cross-contamination and mix-ups.

**Representation on Ensuring a level playing field in New Drug Approval in India**

IDMA submitted the Representation on the level playing field issue on 07th November 2025. DCGI had issued a circular outlining the process for handling first and second applicants for new drug approvals. Upon reviewing the circular, it was observed that the core issue arises when multiple applications are received simultaneously. Under the current system, the first applicant is required to conduct Phase III clinical trials, while subsequent applicants may receive approval based on the data generated by the first applicant. The existing rules clearly distinguish between the requirements for a first applicant and a second applicant. However, processing multiple applications together has created certain discrepancies. Therefore, IDMA recommended that the rules be followed strictly, ensuring that the second and subsequent applicants should rely on the data generated by the first applicant. All subsequent applicants must wait until the first applicant completes the mandated Phase III trial before their applications can be processed. This approach provides the first applicant with sufficient time and protection for the investment, effort and cost incurred in conducting Phase III trials.

**Representation on GSR 756 (E), dt.16.10.2025 with regard to Debarment of application with misleading, or fake, or fabricated documents/information**

IDMA's representation with regard to GSR 756(E) dated 07th November 2025 pertaining to the Debarment of applications involving misleading, fake, or fabricated documents/information. The draft provisions covered several situations that were highly subjective and could lead to misinterpretation. IDMA recommended removing broad terms such as "false information" and limiting the provision strictly to cases involving intentionally submitted fake or falsified documents in support of any application. It was strongly recommended that the scope and duration of debarment be clearly defined and proportionate to the severity of the falsification, rather than being applied uniformly across all cases. IDMA has made a very strong representation on this matter.

**Representation on GSR 757 (E) dt.16.10.2025 wrt Expansion of Schedule H2**

IDMA submitted a Representation on the proposed expansion of Schedule H2, which mandates the use of QR codes/barcodes on 300 specified drugs on 13th November 2025. The barcoding system has been partially implemented as per the notification, there is currently no mechanism to verify the authenticity of these codes. There is no central database or repository where codes are stored, tracked or decommissioned upon dispensing. As a result, the end-to-end traceability mechanism remains incomplete. IDMA highlighted this gap and emphasized that, although awareness creation and affixing of codes on branded packs have progressed well, the system must now be taken to its logical conclusion. A Government-managed central hub must be established

to enable verification, detection of duplicates, and automatic alerts across the regulatory network.

IDMA recommended that only after such a system is fully implemented should any additional categories including life-saving and sensitive drugs be considered for inclusion under Schedule H2. Until then, expansion to these categories should be kept in abeyance. Dr. Amit Rangnekar mentioned that although the QR/barcode system has been implemented on the top 300 drugs for almost three years, awareness and public engagement remain extremely low. Despite the significant effort and investment made by the industry estimated at ₹3–4 crore in total and 30–35 paise per pack only three queries have been received since implementation began. Out of these three queries raised, two were related to practical difficulties (poor lighting for scanning and inability to scan due to not having an Android phone). Only one query pertained to authentication, which clearly demonstrates that the core objective of the system public verification and detection of falsified medicines is not being achieved. The Government must sensitize the public and strengthen the ecosystem, as the current system has not delivered the intended outcomes despite industry-wide compliance and significant expenditure. Dr. Amit Rangnekar mentioned that the authorities are now considering extending the requirement to additional categories such as Nutraceuticals (NDPs), cancer drugs, vaccines, antimicrobials, and more. A new circular has also been issued mandating that, from 1st March 2026, all excipients must be included in the authentication measures for the Top 300 drugs which carry QR codes. He pointed out that this circular was embedded within multiple other notifications, making it difficult for many stakeholders to track and understand its implications. As a result, excipients would now need to be included as part of the “top 300 drugs” QR Code framework with all its other requirements.

**Third meeting of sub-committee to examine the matter related to labelling of medicinal products (agenda 13 of 66th DDC held on 17.06.2025)**

The third meeting of the Sub-Committee constituted to examine matters related to the labelling of medicinal products was held on 18th November 2025. During the meeting, the Committee reviewed several key concerns raised through customer grievances, particularly issues impacting patient safety, readability, and accessibility of medicine labels. The concerns discussed included Damage to expiry labels, Poor readability due to shiny packaging surfaces, small font size used on labels, non-continuous printing of the medicine name, the need for a universal symbol to distinguish generic medicines.

Mr. S M Mudda informed the members that the sub-committee was formed specifically to examine these 4–5 major grievances received from consumers. The discussions also covered broader issues such as Quality and integrity of printing on labels, Compliance and performance of packaging material/component suppliers, The proposal for affixing a special code or symbol to differentiate generic medicines from branded products. Mr. Mudda along with Mr. Rambabu, Chairperson of the Telangana State Board, attended the meeting and presented detailed clarifications supported by existing regulatory provisions, including Rule 96, related pricing

requirements, and Schedule M standards. They explained, these provisions already adequately address most of the concerns raised, and the primary issue lies in effective implementation and verification during inspections by State Drug Authorities.

Mr. S M Mudda mentioned that the meeting was successful and had a positive development that the Sub-Committee accepted all the points presented and acknowledged that the current regulatory framework is sufficient to manage the issues without necessitating amendments to the Rules at this stage. Instead, the Committee agreed that improved enforcement through guidance or circulars to State Drug Inspectors and Controllers would be more practical.

## REPRESENTATIONS SUBMITTED DURING 2025

| S.No. | Subject | Date of submission | Submitted to |
|---|---|---|---|
| 01 | IDMA Suggestions on Draft Notification GSR 10(E) dated 04.01.2025 with reference to Schedule M | 11.01.2025 | The Under Secretary (Drugs), MoHFW |
| 02 | IDMA comments on Minimum Import Price (MIP) proposal for ATS-8 (Intermediate of Atorvastatin API) | 13.01.2025 | DoP |
| 03 | IDMA's comments on India-EU FTA: Rules of Origin – PSRs for Pharma Sector | 27.01.2025 | Mr. Giriraj Prasad Meena, Under Secrtary, DoP |
| 04 | IDMA's suggestions with regard to Reducing Compliance Burden | 30.01.2025 | Dr. Bhuvnesh Prasad Singh, Deputy Secy, DPIIT |
| 05 | IDMA's Comments/suggestions on CPCB's Draft Guidelines for the Pharmaceutical Industry in India | 03.02.2025 | Mr. Dinabandhu Gouda, Scientist F, CPCB |
| 06 | IDMA's Comments/suggestions on CPCB's Draft Guidelines for the Pharmaceutical Industry in India | 03.02.2025 | Mr. Dharmendra Kumar Yadav, Under Secy, DoP |
| 07 | IDMA Representation – Voluntary submission of monthly return – International Special Surveillance List | 05.02.2025 | Mr. Dinesh Bouddh, IRS Narcotics Commissioner, Gwalior |

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| 08 | IDMA's inputs on list of substances reviewed by 47th WHO Expert Committee on Drug Dependence for scheduling recommendations | 07.02.2025 | Dr. Himanshu Roy Director, DoP |
| 09 | IDMA's White Paper on US Tariff Plan and their Implications for the Indian Pharma Industry | 27.02.2025 | Mr. Nitin Yadav, Joint Secretary, Commerce |
| 10 | Creation of New Tariff Lines for Gelatin Grades to Prevent Illicit Diversion | 11.03.2025 | Deputy Secy, DoP |
| 11 | Provisions of Para 24 of DPCO 2013 relating to carrying into effect the price fixed or revised by the Government its display and proof thereof | 17.03.2025 | Secretary DoP & CC to: Sr. Eco Advisor, DoP Chairman NPPA & Cc to: Member Secy, NPPA |
| 12 | NOC Exports: To reconsider requirement for approval status by National Regulatory Authority of importing country for NOC for exports | 20.03.2025 | Secretary, DoP & DCGI |
| 13 | Representation for reconsideration of Ceiling Prices allowing five decimal points for low priced drug | 27.03.2025 | Chairman, NPPA |
| 14 | IDMA's Comments on Recent Ban of Halal Products in Uttar Pradesh | 02.04.2025 | Under Secretary, DoP |
| 15 | NOC Exports Representation on Revised Guidelines for Export NOC for New/ Unapproved drugs | 03.04.2025 | Joint Secretary (H) & DCGI |
| 16 | Issuance of Environmental Clearance (EC) and Consent to Operate (CTO) for the API and Intermediates as single category instead of individual products. | 11.04.2025 | Dr. Amandeep Garg, Addl. Secretary, MoEF |

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| 17 | Feedback & Suggestions on the Proposed "Export Promotion Mission – Enhancing Exports and Supporting MSMEs in Pharmaceuticals | 15.04.2025 | Ms. Palka Sahni, Joint Secretary, DoP |
| 18 | Request for Diplomatic support to Ensure Protection and continuity of Indian Pharmaceutical Operations supplying Essential Medicines in Ukraine | 28.04.2025 | Hon'ble Sh. J P Nadda ji, Minister of Health |
| 19 | Manufacturing and Marketing of unapproved FDCs | 30.04.2025 | DCGI |
| 20 | Representation wrt Guidance & Advice on 'Reference Products for Conduct of BE Studies' | 03.05.2025 | DCGI |
| 21 | Issues concerning exports to Thailand | 09.05.2025 | DoP |
| 22 | Issues concerning Exports to Malaysia | 10.05.2025 | DoP |
| 23 | Looming possibility of shifting of Nutraceutical health vertical, or some segment of it, from under the ambit of FSSAI to either CDSCO and/or AYUSH | 15.05.2025 | Hon'ble Chirag Paswan, Minister of Food Processing Industries Cc to: CEO, FSSAI |
| 24 | Reply to Lok Sabha question wrt What are the precise public health and economic ramifications of spurious and fake medicines on India's pharmaceutical sector | 30.05.2025 | Lok Sabha |
| 25 | Enhancing India's Pharmaceutical Exports to Australia | 04.06.2025 | DoP |
| 26 | Inputs wrt Vietnam | 05.06.2025 | DoP |
| 27 | Inputs wrt Mauritius | 05.06.2025 | DoP |
| 28 | IDMA's request for withdrawal/modification of Office Order, dated 28.5.2025 restricting entry of MRs in Central Government Hospital | 12.06.2025 | Dr. Sunita Sharma, DGHS |

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| 29 | IDMA's Inputs with regard to Brazil, Argentina, Uruguay, Trinidad & Tobago, Morocco and BRICS Summit | 19.06.2025 | DoP |
| 30 | IDMA's inputs with regard to Uzbekistan | 25.06.2025 | DoP |
| 31 | IDMA Representation for MSME limits of 500 Cr classification: 25.06.2025 with regard to Schedule M implementation | 25.06.2025 | DCGI |
| 32 | IDMA's submission on proposed measures relating to NSQ products and suspension of Licenses | 01.07.2025 | DCGI |
| 33 | IDMA Representation: Streamlining of NOC Procedures for Export of Drugs and FDCs | 10.07.2025 | DCGI |
| 34 | FTA negotiations with Australia and New Zealand | 14.07.2025 | DoP |
| 35 | Inputs with regard to Namibia | 14.07.2025 | DoP |
| 36 | Inputs with regard to Romania | 14.07.2025 | DoP |
| 37 | Proposal for making BIS standard mandatory for Salicylic Acid (Technical) | 17.07.2025 | DoP |
| 38 | Submission of Compliance Report under UCPMP 2024 | 23.07.2025 | JS, DoP |
| 39 | Inputs with regard to Japan | 06.08.2025 | DoP |
| 40 | Inputs with regard to Oman | 12.08.2025 | DoP |
| | Inputs with regard to India-UAE High Level Task Force on Investment (HLTFI) | 12.08.2025 | DoP |
| 41 | Grant of WHO GMP COPP through ONDLS Portal | 18.08.2025 | DCGI |

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| 42 | Grant of WHO GMP COPP through ONDLS Portal | 18.08.2025 | Mr. Nitin K Yadav, Addl. Secretary, Ministry of Commerce |
| 43 | Inputs with regard to Singapore | 22.08.2025 | DoP |
| 44 | DoP Questionnaire for Inclusion of Non Scheduled Precursor Chemicals under Schedule-A of Regulation of Controlled Substances Order of NDPS Act, 1985 | 01.09.2025 | Mr. Dharmendra Kumar Yadav, Under Secretary, DoP |
| 45 | IDMA Representation to align GST rate on API to prevent Inverted Duty Structure and Extension for Implementation of revised MRP | 01.09.2025 | Hon'ble Finance Minister; Addl. Secy, GST Council Secrett, Chairman CBIC Chairman NPPA |
| 46 | IDMA Representation - To Extend the Time Limit for Payment under Section 15 of the MSME Development Act, 2006 and allow the deduction of section 43B(h) and corresponding 37(2)(g) of Income Tax Bill 2025 if paid before the due date of filing return | 02.09.2025 | Hon'ble Minister of MSME<br>Hon'ble Finance Minister |
| 47 | Inputs wrt Fiji | 03.09.2025 | DoP |
| 48 | Inputs for 7th meeting of Hungarian-Indian Joint Commission on Economic Cooperation (JCEC) | 03.09.2025 | DoP |
| 49 | IDMA's inputs with regard to India-EU Rules of Origin | 09.09.2025 | DoP |
| 50 | Inputs with regard to Ethambutol Hydrochloride | 11.09.2025 | DoP |
| 51 | Permanent Mission of India to the WTO Side event on "TRIPS implementation and Public Health and the TRIPS | 12.09.2025 | DoP |

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| 52 | Compliance reduction, Deregulation and Ease of Doing Business in States | 15.09.2025 | Director, DoP |
| 53 | Inputs with regard to 19th Session of India Bulgaria Joint Commission for Economic, Scientific and Technical Cooperation (JCESTC) | 16.09.2025 | DoP |
| 54 | Inputs with regard to Interaction on Expanding India's Exports to Russia | 16.09.2025 | DoP |
| 55 | IDMA representation to CDSCO Circular letter dt. 11.9.2025 with regard to Withdrawal / Cancellation of product permission for not implementing GSR 327 (E), dated 3.4.2017 | 18.09.2025 | DCGI |
| 56 | Representation with regard to GSR 425 (E), dated 19.7.2024 | 30.09.2025 | Secretary, MoEF |
| 57 | Rep. for extension of implementation of Revised Schedule M | 03.10.2025 | DCGI |
| 58 | Input with regard to Critical minerals | 24.10.2025 | DoP |
| 59 | Inputs with regard to Anti-dumping investigation concerning import of 4(Bromomethyl)-2 Cyanobiphenyl (Bromo OTBN) | 27.10.2025 | DoP |
| 60 | Notes on API & Intermediates Category and Production Enhancement without Pollution load increase | 27.10.2025 | Mr. Aditya Narain Singh, Scientist E, MoEF & CC |
| 61 | Input with regard to Angola | 28.10.2025 | DoP |
| 62 | Inputs with regard to South Africa | 28.10.2025 | DoP |
| 63 | Inputs with regard to Mercury | 30.10.2025 | DoP |
| 64 | Inputs with regard to Bhutan | 04.11.2025 | DoP |

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| 65 | Representation on Ensuring a level playing field in New Drug Approval in India | 07.11.2025 | DCGI |
| 66 | Representation on GSR 756 (E), dt.16.10.2025 with regard to Debarment of application with misleading, or fake, or fabricated documents/information | 07.11.2025 | Director (Drugs Regulations) Ministry of Health & Family Welfare |
| 67 | Representation with regard to Risk-Based clarification on mandatory DEG/EG testing for all Oral Liquid Formulations | 10.11.2025 | DCGI |
| 68 | Information with regard to Iso-Propyl Alcohol | 11.11.2025 | DoP |
| 69 | IPDMS – feedback of the industry on the functionality of IPDMS | 13.11.2025 | Joint Director, DoP |
| 70 | Representation on GSR 757 (E), dt.16.10.2025 wrt Expansion of Schedule H2 | 13.11.2025 | Director (Drugs Regulations) Ministry of Health & Family Welfare |
| 71 | Information wrt India-Poland Joint Commission on Economic Cooperation | 14.11.2025 | DoP |
| 72 | Information wrt India – Greece Joint Economic Committee (JEC) | 14.11.2025 | DoP |
| 73 | Information wrt India – Myanmar Joint Trade Committee meeting | 14.11.2025 | DoP |
| 74 | Details of nodal person for API / Bulk drug industry members | 19.11.2025 | DoP |
| 75 | Inputs wrt Switzerland | 24.11.2025 | DoP |
| 76 | Inputs wrt Indonesia | 24.11.2025 | DoP |

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| 77 | Representation - Retaining Nutraceuticals [encompassing Health Supplements, Nutraceuticals (per se), Food for Special Dietary Use (FSDU), Food for Special Medical Purpose (FSMP), Functional Food, and Novel Food] under the ambit of MoFPI for planning, development, segment growth and exports & doing away with overlapping regulatory control by CDSCO and AYUSH | 25.11.2025 | Hon'ble Sh. Chirag Paswan, Minister of Food Processing Industries |
| 78 | Inputs wrt Laos | 26.11.2025 | DoP |
| 79 | Inputs wrt Oman | 26.11.2025 | DoP |
| 80 | Inputs/Comments on New Reports wrt India-UK Comprehensive Economic and Trade Agreement | 26.11.2025 | DoP |
| 81 | Proposed Regulatory Data Protection (RDP) / Data Exclusivity (DE) | 27.11.2025 | Secretary, DoP |
| 82 | Inputs wrt Jordan | 28.11.2025 | DoP |
| 83 | Inputs wrt India-Taipei Economic Consultation | 02.12.2025 | DoP |
| 84 | Inputs wrt first session of India-Rwanda Joint Trade Committee | 03.12.2025 | DoP |
| 85 | Inputs wrt Lok Sabha question No.2108 to be answered on 12.12.2025 | 08.12.2025 | DoP |
| 86 | Inputs wrt Ethiopia | 09.12.2025 | DoP |
| 87 | Inputs wrt Lok Sabha question No.2136 to be answered on 12.12.2025 | 11.12.2025 | DoP |
| 88 | Information wrt Trade Generics | 15.12.2025 | DoP |

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| 89 | Suggestions/proposals : Information wrt Vietnam | 19.12.2025 | DoP |
| 90 | Input for a VVIP visit from Honduras to India | 19.12.2025 | DoP |
| 91 | Discussion on possible Investment and Collaboration in Sri Lanka's Health Sector | 19.12.2025 | DoP |
| 92 | Request for extension for existing applicants under GSR 10 (E) and opportunity to file new Upgradation Plan by MSMEs - Revised Schedule M | 22.12.2025 | DCGI |
| 93 | Request for extension for existing applicants under GSR 10 (E) and opportunity to file new upgradation plan by MSME – Revised Schedule M | 23.12.2025 | Secretary (Health)<br>Cc : JS – Health<br>Director (Drug Regulations) |
| 94 | IDMA's inputs with regard to Germany | 26.12.2025 | DoP |

## MEETINGS, WEBINARS AND SEMINARS IN 2025

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| 04.01.2025 | 40th Foundation Day celebrations of DSIR at Dr. Ambedkar International Centre, Conference Centre, Janpath Road, Delhi | Mr. Ashok Madan |
| 07.01.2025 | DoP - Meeting of the Technical Committee constituted to support in preparation of Action Plan under the Action Plan Team on Healthcare/ Pharmaceuticals under Indo- Pacific Economic Framework for Prosperity (IPEF) Agreement | Mr. Ashok Madan |
| 09.01.2025 | Meeting with Mr. Aditya Narain Singh, Scientist 'F' MoEF | Mr. Ashok Madan |
| 15.01.2025 | Meeting with Mr. Amit Agrawal, Secretary, DoP | Mr. Ashok Madan |
| 16.01.2025 | VC meeting with regard to Section 65 (1) of Customs Act by DoP | Mr. Ashok Madan |

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| 20.01.2025 | VC meeting on Reducing Compliance Engagement with Industry Associations – by DPIIT | Mr. Ashok Madan |
| 21.01.2025 | Meeting with Chairman, NPPA, Member Secretary, NPPA, Mr. Awadhesh Choudhary, Sr. Eco. Advisor, DoP | Mr. Ashok Madan |
| 23.01.2025 | Industry consultation with CDSCO | Dr. Viranchi Shah Dr. George Patani, Mr. S.M. Mudda & Mr. Ashok Madan |
| 24.01.2025 | IDMA's First National Executive Committee meeting of 2025 | |
| 31.01.2025 | Stakeholders' consultation meeting of Secretary (Health) | Mr. S.M. Mudda, Mr. Ashok Madan |
| 08.02.2025 | IDMA's 2nd EC meeting and 63rd Annual Day Celebrations at Mumbai | |
| 11.02.2025 | DoP meeting on UCPMP 2024 | Dr. Viranchi Shah |
| 11.02.2025 | Commerce - Hybrid meeting of Committee to review Pharma and Medical Devices trade performance | Mr. Sundeep Bambolkar |
| 14.02.2025 | CDSCO - Meeting on extension of implementation of the revised schedule-M and demo for filing the application seeking extension on ONDLS portal | Mr. S.M. Mudda Mr. Ashok Madan |
| 14.02.2025 | NDPS - Meeting with Mr. Anand Prakash Tiwari, IPS, Deputy Director General (Special Wing), Narcotics Control Bureau | Mr. Devesh Malladai |
| 17.02.2025 | CPCB - VC meeting regarding modified 'Draft Guidelines for the Pharmaceutical Industry in India' | Mr. Yogin Majmudar, Mr. Suresh Raju Penmente & Mr. Ashok Madan |
| 19.02.2025 | Swadeshi Jagran Manch - Advancing Affordable Healthcare – Transformative Potential of Biosimilars in India | Mr. Ashok Madan |

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| 21.02.2025 | DoP - Hybrid meeting to discuss impetus to manufacture of Chemicals needed by Pharma for API production | Mr. Yogin Majmudar, Mr. Manish Doshi Mr. Ashok Madan |
| 21.02.2025 | DoP - Second Meeting (VC mode) of the Technical Committee under IPEF Action Plan Team (Healthcare/ Pharmaceuticals) | Mr. Mehul Shah Mr. Ashok Madan |
| 25.02.2025 | Reception at British High Commission @ Bungalow 3, British High Commission, Shantipath, Chanakyapuri, New Delhi. | Mr. Ashok Madan |
| 26.02.2025 | Meeting with MHRA delegates at Hotel JW Marriott, Juhu, Mumbai<br>MHRA Delegates:<br>• James Pound, Interim Executive Director, Innovation and Compliance<br>• Emanuela Krasteva, Lead Senior GDP Inspector<br>• Trevor Watson, Lead Senior GMP Inspector<br>Accompanied by: Dr. Himangi Bhardwaj, Head – Health & Lifesciences, British High Commission, New Delhi | Ms. Aditi Panandikar |
| 27.02.2025 | India & Arab Countries Chamber of Commerce, Industry and Agriculture – Introductory Ceremony, at ITC Maurya, Delhi | Mr. Ashok Madan |
| 28.02.2025 | IPC - Regional Training Programme on Implementation of Pharmacovigilance Guidance Document (Version 2.0) @ CDTL, Mumbai | Dr. George Patani |
| 06.03.2025 | Meeting with US Embassy officials –<br>Dr. Supratim Chatterjee, Economic Specialist,<br>Mr. Aditya Phatak, Political Specialist &<br>Mr. Dhruv Shah, Sr. Technical Advisor, USFDA | Mr. Ashok Madan |
| 07.03.2025 | IDMA's 2nd EC meeting at Ahmedabad & GSB Annual Day Celebrations | |
| 07.03.2025 | DoP - VC Meeting to discuss classification and creation of new tariff lines for Gelatin grades to prevent illicit diversion | Mr. Ajit Singh Ji and Mr. Ketan Parmar from ACG |

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| 10.03.2025 | Meeting with Dr. (Mrs.) Vinod Kotwal, Member Secretary NPPA | Mr. Ashok Madan |
| 18.03.2025 | DBT /BIRAC - Meeting with H E Dr. Eduardo Martinez, Deputy Prime Minister, CUBA and delegation at Delhi | Mr. Ashok Madan |
| 20.03.2025 | Meeting with Dr. Amandeep Garg, Addl. Secretary, MoEF | Mr. Suresh Raju & Mr. Ashok Madan |
| 25.03.2025 | DoP - Hybrid meeting on use of domestic petroleum industry products for pharmaceutical industry | Mr. Yogin Majmudar |
| 26.03.2025 | DoP - Online meeting on Chemical Value Chain | Mr. Yogin Majmudar |
| 02.04.2025 | CDSCO - VC meeting for Simplification of license procedure for drugs/IND/BA-BE studies | Dr. Kiran Marthak Mr. Daara Patel, Mr. Ashok Madan |
| 07.04.2025 | Second meeting of NIPER Council – VC mode | Mr. Bharat N Shah |
| 08.04.2025 | IDMA delegation meetings with following officials:<br>• Shri Amit Agrawal, IAS, Secretary, DoP<br>• Shri Awadhesh Choudhary, IES, Senior Economic Adviser & Additional Secretary, DoP<br>• Dr. Himanshu Roy, IRS, Director, DoP<br>• Mr. Raghu Kumar Kodali, Scientist G, Ministry of Environment<br>• Mr. Ranga Chandershekhar, Joint Drugs Controller (India), CDSCO<br>• Shri Rajeev Wadhawan, Joint Secretary (Health)<br>• Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)<br>• Mr. P. Krishnamurthy, Chairman, NPPA<br>• Dr. (Ms) Vinod Kotwal, Member Secretary, NPPA<br>• Mr. Sanjay Kumar, Adviser, NPPA | Mr. Bharat N Shah Dr. Viranchi Shah Ms. Aditi Panandikar Mr. Mehul Shah Dr. George Patani Mr. Ashok Madan |
| 16.04.2025 | Commerce - 2nd Monthly Meeting to review trade performance of Pharma and Medical Devices -- VC meeting | Mr. Sundeep Bambolkar Mr. Ashok Madan |
| 17.04.2025 | IDMA's 2nd EC meeting by VC mode | |

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| 21.04.2025 | CDSCO - WHO SEARN proposed convergence mechanism on Marketing Authorization - Preliminary informal consultation with Industry | Mr. S.M. Mudda<br>Mr. Ashok Madan |
| 21.04.2025 | DoP - VC Meeting to facilitate industry/ Academia collaboration to promote R&D | Mr. Probhas B Chakraborty<br>Mr. Ashok Madan |
| 23.04.2025 | DoP - VC meeting wrt opinions on the Selection of Items for the IPEF CRN Tabletop Exercise (First Half of the Year) | Mr. Yogin Majmudar<br>Mr. Ashok Madan |
| 24.04.2025 | Meeting of Nutraceuticals Committee of CDSCO | Mr. S.M. Mudda |
| 25.04.2025 | DoP -- Meeting to review the Guidelines issued by Department of Pharmaceuticals for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017 | Mr. Ashok Madan<br>Ms. Sapna Patil |
| 26.04.2025 | Meeting of Consultations with Industry Associations - National Mission on Manufacturing Commission at NITI AAYOG | Mr. Ashok Madan |
| 27.04.2025 | World Health Summit Regional Meeting | Mr. Ashok Madan |
| 07.05.2025 | FSSAI's consultation meeting on Nutraceuticals | Dr. R.K. Sanghavi,<br>Mr. Ganesh Kamath,<br>Mr. Ashok Madan |
| 08.05.2025 | DoP - Online meeting on India-UK Trade Agreement | Mr. Sundeep Bambolkar,<br>Mr. Ashok Madan |
| 08.05.2025 | CPCB -- VC meeting for coordinating with industry associations for seeking inputs on OCEMS Calibration Guidelines | Mr. Yogin Majmudar<br>Mr. Ashok Madan |
| 13.05.2025 | Commerce -- 3rd Monthly Meeting to review the trade performance of Pharma and Medical Devices (Online) | Mr. Sundeep Bambolkar,<br>Mr. Ashok Madan |

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| 14.05.2025 | DoP / IDMA Webinar on GMP and RPTUAS Scheme @ Bangalore | |
| 16.05.2025 | CDSCO - Meeting wrt various amendments in Drugs Rules, 1940 | Mr. S.M. Mudda<br>Mr. Nilesh Gandhi |
| 17.05.2025 | CDSCO - Online meeting for Consideration of the proposal for suspension of product permission declared Not of Standard Quality Drug by a Government Analyst of Government Testing Laboratory | Mr. S.M. Mudda |
| 17.05.2025 | IDMA's Executive Committee meeting | |
| 19.05.2025 | DoP /C-DEP -- Pre-Conclave meeting on Roundtable on Securing Pharmaceutical Sovereignty | Mr. Ashok Madan |
| 20.05.2025 | Meeting with Chairman NPPA | Mr. Ashok Madan |
| 20.05.2025 | DoP /IDMA -- Webinar on GMP and RPTUAS Scheme @ Hyderabad | |
| 21.05.2025 | Meeting with Dr. Hafsa Ahmad, Scientist D, PSA | Mr. Ashok Madan |
| 23.05.2025 | DoP / C-DEP -- Roundtable on Securing Pharmaceutical Sovereignty | Mr. Bharat N Shah,<br>Mr. Ashok Madan |
| 26.05.2025 | DoP -- VC meeting regarding UCPMP Portal | Ms. Sapna Patil<br>Mr. Melvin Rodrigues |
| 27.05.2025 | DoP -- Stakeholder consultation regarding supply chain issues – IPEF Action Plan Team: VC meet | Mr. Yogin Majmudar<br>Mr. Ashok Madan |
| 27.05.2025 | DoP /IDMA -- Webinar on GMP and RPTUAS Scheme @ Ahmedabad | |
| 28.05.2025 | Meeting with Dr. Arunish Chawla, Secretary, Dept. of Investment and Public Asset Management | Mr. Ashok Madan |

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| 28.05.2025 | DoP -- VC Meeting to facilitate industry/ Academia collaboration to promote R&D | Mr Probhas B Chakraborty<br>Mr. Ashok Madan |
| 29.05.2025 | DoP /IDMA -- Webinar on GMP and RPTUAS Scheme @ Baddi | |
| 30.05.2025 | DoP /IDMA -- Webinar on GMP and RPTUAS Scheme @ Vadodara | |
| 30.05.2025 | ISID - Policy Roundtable on “Product Patents in the Pharmaceutical Sector in India: A Reflection on 20 Years – ISID premises – Hybrid mode | Mr. Bharat N Shah<br>Dr. Gopakumar Nair<br>Mr. Ashok Madan |
| 11.06.2025 | FICCI -- VC meeting on Prime Ministers’ Internship Scheme | Mr. Ashok Madan |
| 12.06.2025 | ISID -- Seminar on Indian Health Economic & Industrial Complex since Covid 19 Reflections on Global South – Hybrid mode | Mr. Ashok Madan |
| 13.06.2025 | Commerce - 4th monthly meeting EXPORT COMMITTEE to review the trade performance of Pharma and Medical Devices | Mr. Ashok Madan |
| 16.06.2025 | IPC -- Inauguration Ceremony of “2nd Policymakers’ Forum” at Sushma Swaraj Bhawan, New Delhi | Mr. Ashok Madan |
| 16.06.2025 | DoP -- VC Meeting under the chair of Joint Secretary, Department of Pharmaceuticals regarding UCPMP Portal | Ms. Sapna Patil |
| 17.06.2025 | Meeting with Dr. Vinod K Paul, Member NITI Aayog | Mr. Ashok Madan |
| 17.06.2025 | Meeting with Ms. S. Ahlladini Panda, Member Secretary, NPPA | Mr. Ashok Madan |
| 18.06.2025 | DoP -- VC meeting to discuss the Rules of Origin - PSRs for Pharma Sector under India-EU FTA | Dr. Gopakumar Nair,<br>Mr. Kiran Rumde (Indoco),<br>Mr. Ashok Madan |

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| 20.06.2025 | IDMA Executive Committee meeting @ Mumbai VC mode | |
| 23.06.2025 | Virtual meeting with Ministry of Investment, Saudi Arabia in coordination with Embassy of India, Riyadh | |
| 23.06.2025 | CDSCO -- Training Session on ONDLS by CDSCO, Western Zone in collaboration with IDMA @ Jade Ballroom, Mumbai | |
| 03.07.2025 | 249th Anniversary of Independence Day reception of US | Mr. Bharat N Shah |
| 04.07.2025 | Meeting with Mr. Hemant Kumar Meena, Director NITI Aayog | Mr. Ashok Madan |
| 07.07.2025 | Visit of National President, IDMA for:<br>1. NITI Aayog Consultation on Raising the Quality of Indian Pharmaceutical Products to Global Standards;<br>2. Meeting with Dr. Rajeev Singh Raghuvanshi, DCGI | Mr. Bharat Shah<br>Dr. Viranchi Shah<br>Mr. Kamlesh Patel<br>Mr. Nirav Mehta<br>Mr. Ashok Madan |
| 09.07.2025 | 11th meeting of the General Body of IPC @ Nirman Bhawan | Mr. Ashok Madan |
| 10.07.2025 | CDSCO -- Hybrid meeting To demonstrate the procedure of online application for grant of WHO-GMP COPP through ONDLS portal | Mr. Ashok Madan |
| 11.07.2025 | Commerce -- 5th monthly meeting to review trade performance of Pharma and Medical Devices – Hybrid meet – Conference room No.13, Vanijya Bhawan | Mr. Ashok Madan |
| 11.07.2025 | IPC -- Meeting with Mr. V. Kalaiselvan, Secretary-cum-Director IPC, Ghaziabad | Mr. Ashok Madan |
| 15.07.2025 | DoP -- VC meeting on India US Bilateral Trade Agreement | Mr. Ashok Madan |
| 15.07.2025 | DoP -- Industry Discussion Points concerning data collection under UCPMP 2024 (VC meet) | Mr. Ashok Madan |

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| 17.07.2025 | CDSCO -- Meeting with Dr. Rajeev Singh Raghuvanshi, DCGI @ FDA Bhawan | Dr. Viranchi Shah<br>Mr. Mehul Shah<br>Mr. Ashok K Madan |
| 17.07.2025 | Meeting with Hon'ble Sh. Piyush Goyal, Minister of Commerce & Industry at Vanijya Bhawan | Dr. Viranchi Shah<br>Mr. Mehul Shah<br>Mr. Ashok K Madan |
| 17.07.2025 | DoP -- Hybrid meeting discuss the proposal for imposition of Minimum Import Price (MIP) on ATS-8 and other APIs | Mr. Manish Doshi<br>Mr. Hemant Joshi |
| 18.07.2025 | IDMA's 5th National Executive Committee meeting at Mumbai | |
| 30.07.2025 | LSSSDC -- Governing Body and Annual General Meeting of Life Sciences Sector Skill Development Council | |
| 31.07.2025 | Meeting with Mr. Nitin K Yadav, Addl. Secy. Commerce | Mr. Ashok K Madan |
| 31.07.2025 | Pharmexcil -- Curtain Raiser Ceremony of iPHEX 2025 – 11th International Exhibition and Healthcare | Mr. Ashok K Madan |
| 05.08.2025 | Mr. K.K. Tripathy, Joint Secretary, Economic Advisory Council to Prime Minister | Mr. Ashok K Madan |
| 06.08.2025 | FICCI -- India – Philippines CEOs Roundtable - State Visit of H.E. Ferdinand Romualdez Marcos Jr., President of the Republic of the Philippines | Mr. Bharat N Shah<br>Mr. Ashok Madan |
| 07.08.2025 | DSIR -- Consultative meeting on the achievements and challenges of DSIR's extramural schemes – Hybrid meeting | Dr. George Patani<br>Mr. Ashok Madan |
| 08.08.2025 | Commerce -- VC meeting to discuss EFTA agreement | Mr. Ashok K Madan |
| 13.08.2025 | FSSAI - 3rd National Stakeholders consultation on Comprehensive Analysis of Regulatory Framework on Food labelling, Advertisement and Claims at Vigyan Bhawan | Dr. R.K. Sanghavi |

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| 14.08.2025 | Commerce -- Industry Interaction with the Hon'ble Minister for Commerce & Industry, Shri Piyush Goyal @ Vanijya Bhawan, New Delhi | Mr. Bharat Shah<br>Ms. Aditi Panandikar<br>Dr. Viranchi Shah<br>Mr. Mehul Shah<br>Mr. Manish Doshi<br>Mr. Ashok Madan |
| 16.08.2025 | IDMA's National Executive Committee meeting @Chennai – Hybrid meet | |
| 19.08.2025 | CII's Webinar on Belarus – India: Promising Areas Of Cooperation | Mr. Ashok Madan |
| 21.08.2025 | Pharmarack -- Zoom meeting on Biologics and Biosimilars Changing the Canvas of Indian Pharma Market | Mr. Ashok Madan |
| 22.08.2025 | Health - Meeting with Dr. Kiran Karlapu, Director Health | Mr. Ashok Madan |
| 27.08.2025 | Health - Meeting with Dr. (Mrs.) Vinod Kotwal, Addl. Secy (H) | Mr. Ashok Madan |
| 28.08.2025 | DoP -- Online preparatory meeting vis-a-vis the interaction with the incoming Trade Mission from the Netherlands Chaired by Ms. Gayatri Nair, Economic Advisor, DoP | Mr. Ashok Madan |
| 01.09.2025 | DoP -- Interaction with the Trade Mission from the Netherlands | Mr. Nitin Garg (Indoco)<br>Ms. Upasana (Glenmark)<br>Ms. Himanshi Kaushik (Mankind)<br>Mr. Ashok Madan |
| 01.09.2025 | DoP -- VC meeting to discuss the India – United Kingdom Comprehensive Economic and Trade Agreement (CETA) | Mr. Daara B Patel |
| 04.09.2025 | Pharmexcil -- IPhex 2025 at Bharat Mandapam | Mr. Ashok Madan |

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| 08.09.2025 | Meeting with US delegation at US Embassy | Mr. Ashok Madan |
| 10.09.2025 | Finance -- Meeting on GST reforms, rate rationalization and their implementation @ Kalpavriksha, Room No. 158-A, 1st Floor, North Block | Mr. B.G. Barve<br>Mr. C.V. Venkatraman<br>Mr. Pramod Ghorpade<br>Mr. Ashok K Madan |
| 11.09.2025 | DoP -- Meeting to explore the feasibility of a common pharmacopeia for the IPEF region | Dr. Vinay Naik,<br>Mr. Milind Joshi<br>Mr. Ashok K Madan |
| 11.09.2025 | DoP's VC meeting on Compliance reduction, Deregulation and Ease of Doing Business in States | Mr. Bharat Shah<br>Dr. Viranchi Shah<br>Mr. S.M. Muda<br>Mr. Sanchit Chaturvedi<br>Mr. Prabas Chakraborthy<br>Mr. Paresh Chawla<br>Mr. KV Rambabu<br>Mr. Sumit Agrawal<br>Mr. Ashok Madan<br>Ms. Sapna Patil & others |
| 11.09.2025 | NPPA VC mode - Stakeholder meeting on implementation of the revised GST rates for pharmaceuticals products | Mr. Bharat Shah<br>Mr. Amit Rangnekar |
| 12.09.2025 | DoP -- VC meeting on UCPMP and Related IT Preparation | |
| 12.09.2025 | Meeting with Mr. Nikhil Gajraj, Joint Secretary Health | Mr. Ashok K Madan |
| 12.09.2025 | Meeting with Mr. Sanjay Kumar, Adviser, NPPA | Mr. Ashok K Madan |
| 15.09.2025 | DPIIT -- IP and Free Trade Agreements: Demystifying the IPR Chapter in the India–UK CETA | Mr. Ashok K Madan |

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| 22.09.2025 | DoP's VC meeting to discuss issues pertaining to Vietnam | Mr. Vaibhav Sinha<br>Mr. Ashok K Madan |
| 23.09.2025 | DoP -- Online meeting wrt proposal for imposition of MIP on imports of Potassium Clavulanate and its intermediates | Mr. Yogin Majmudar<br>Ms. Neha Thakore<br>Mr. Ashok K Madan |
| 24.09.2025 | CDSCO -- Second meeting of sub-committee to examine the matter related to labelling of medicinal products | Mr. K.V. Rambabu<br>Mr. Ashok K Madan |
| 26.09.2025 | DoP -- VC meeting to discuss the fall in export of Indian Pharmaceutical products to USA as per latest GTRI report | Mr. Mehul Shah,<br>Mr. Murlidharan (Encube),<br>Mr. Sundeep Bambolkar<br>Mr. Ashok Madan |
| 06.10.2025 | DoP -- VC meeting on PRIPS portal registration | Mr. Ashok Madan |
| 07.10.2025 | Meeting with Mr. Rajit Punhani, CEO FSSAI | Dr. R.K. Sanghavi<br>Mr. G. Kamath & others. |
| 07.10.2025 | DoP -- VC meeting regarding management of quality of critical solvent like propylene glycol | Mr. Bharat Shah<br>Dr. Viranchi Shah<br>Mr. S.M. Mudda<br>Mr. Milind Joshi<br>Mr. Daara Patel<br>Mr. Ashok Madan |
| 07.10.2025 | Meetings with<br>Mr. Nitin K Yadav, Addl. Secretary Commerce<br>Mr. Rajesh Kumar, Deputy Secretary<br>Mr. Y P Dhewal, Director<br>Ms. Jaya Chaudhary, Under Secretary<br>Mr. Vaibhav Bajaj<br>Meeting in Udyog Bhawan, -- Ms. Gayatri Nair<br>Meeting with Mr. Satyaprakash T.L, Jt. Secy, DoP | Mr. Ashok Madan |

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| 13.10.2025 | Visit of IDMA delegation to Delhi | Mr. Bharat Shah<br>Dr. Viranchi Shah<br>Mr. Mehul Shah |
| 15.10.2025 | Sweden Day Reception 2025 @ Ambassador's Residence Garden, Embassy of Sweden, 4-5 Nyaya Marg, Chanakyapuri | Mr. Ashok Madan |
| 16.10.2025 | DoP -- VC meeting on identifying critical Bulk Drugs | Mr. Ashok Madan |
| 17.10.2025 | Executive Committee meeting of IDMA | |
| 30.10.2025 | Commerce -- Interaction with Industry Associations w.r.t Supply Chain Resilience | Mr. Ashok Madan |
| 31.10.2025 | DoP -- VC meeting with the Secretary, Dept. of Pharmaceuticals and the Secretary, Dept. of Health Research on PRIP | Mr. Ashok Madan |
| 06.11.2025 | MoFPI -- Meeting on Nutraceutical under the Chairmanship of Shri Devesh Deval, Joint Secretary, MoFPI | Dr. R.K. Sanghavi<br>Mr. Ganesh Kamath |
| 12.11.2025 | Meeting with Mr. Deep Pant, Deputy Secretary (Health) | Mr. Ashok Madan |
| 13.11.2025 | Meeting with Dr. Neena Malhotra, Secretary (South), MEA | Mr. Ashok Madan |
| 13.11.2025 | IDMA -- AI-Driven Pharma Innovation Summit 2025 @ Hyderabad | |
| 17.11.2025 | Finance -- Pre-budget meeting for Budget 2026-27 | Ms. Ketki Wadhwa,<br>Mr. Sandip Sharma<br>Mr. Ashok Madan |
| 18.11.2025 | DGFT -- Stakeholders consultation with MIP on import of Potassium Clavulanate and its intermediates | Mr.Ashok K Madan |
| 19.11.2025 | DPIIT -- Stakeholders Consultation with Secretary, DPIIT on Regulatory Data Protection (RDP) in Vanijya Bhawan, | Advt. Mahesh Mahadgut<br>Mr. Ashok K Madan |

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| 21.11.2025 | 10th Executive Committee meeting of IDMA (Virtual) at Mumbai | |
| 24.11.2025 | DPIIT -- Round table conference with Hon'ble Minister of Commerce and Industry with CEOs of Pharmaceutical Sector (Domestic) on Regulatory Data Protection (RDP) | Dr. Viranchi Shah<br>Dr. S.V. Veeramani<br>Mr. Ashok K Madan |
| 28.11.2025 | Meeting with Chairman NPPA | Mr. Ashok Madan |
| 01.12.2025 | Meeting with Member Secretary NPPA | Mr. Ashok Madan |
| 01.12.2025 | Commerce -- Meeting with Mr. Mohit Yadav,<br>Joint Secretary | Mr. Ashok Madan |
| 04.12.2025 | FDA- Indian Industry Roundtable on Quality Management Maturity & Pharmaceutical Quality @ Hyderabad | IDMA Telangana State Board |
| 04.12.2025 | IDMA -- Meeting with Members of Telangana State Board at Hyderabad | IDMA Telangana State Board |
| 05.12.2025 | FICCI - Virtual interaction with Ambassador Ajit Gupte, Indian Ambassador to Germany | Mr. Ashok Madan |
| 06.12.2025 | FICCI - Roundtable on Pharmaceuticals and Healthcare: New Opportunities for Russian-Indian Cooperation @ Bharat Mandapam, New Delhi | Mr. Navin Saxena<br>Mr. B.A. Patil<br>Mr. Anmol Johri<br>Mr. Ashok Madan |
| 09.12.2025 | FICCI Committee Meeting on Trade-related Regulatory Reforms | Mr. Ashok Madan |
| 16.12.2025 | Stakeholder Consultation to discuss Proposal for imposition of MIP on Penicillin G, 6-Aminopenicillanic Acid (6-APA) and Amoxicillin Trihydrate for a period of one year from the date of notification | Mr. Ashok Madan |
| 16.12.2025<br>&<br>17.12.2025 | IDMA 24th Pharmaceutical Analysts' Convention (PAC) 2025 at Hotel Sahara Star, Mumbai | |

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| 17.12.2025 | Interactive Business Session with H.E. Mr Mawlawi Noor Jalal Jalili, Hon'ble Minister of Public Health, Emirate of Afghanistan | Mr. Ashok Madan |
| 19.12.2025 | IDMA Executive Committee meeting @ Mumbai | |
| 23.12.2025 | DoP -- VC meeting on Tariff lines – India EU FTA | Mr. Kiran Rumde |
| 24.12.2025 | Health -- Meeting with Mr. Harsh Mangla, JS – Health & Dr. Kiran K Karlapu, Director (Health) | Mr. Ashok Madan |
| 26.12.2025 | Meeting with Mr. Manoj Joshi, IAS<br>Secretary, Department of Land Resources | Mr. Ashok Madan |

## APPOINTMENTS DURING THE YEAR 2025

**February 2025**

- The Appointments Committee of the Cabinet has approved the appointment of Ms. Petal Dhillon (IRTS: 2002) as Joint Secretary, Department of Commerce, vide DoPT order dated 01.02.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Mr. Abhinav Gupta, IRS (2004) as Additional Director General, DGFT, vide DoPT order dated 01.02.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Ms. Madhu Rani Teotia, IAS (UT: 2008) as Additional CEO (JS level), National Health Authority, Department of Health & Family Welfare, vide DoPT order dated 01.02.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Mr. Sanjay Mehrishi, IOFS (1991) as Joint Secretary, National Health Authority, Department of Health & Family Welfare, vide DoPT order dated 01.02.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Mr. Vijay Nehra, IAS (GJ: 2001) as Joint Secretary, Department of Health & Family Welfare, vide DoPT order dated 01.02.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Mr. Pankaj Kumar, ITS (1991) as Joint Secretary (Logistics), Department for Promotion of Industry and Internal Trade, Ministry of Commerce & Industry, vide DoPT order dated 01.02.2025.

**March 2025**

- The Appointments Committee of the Cabinet has approved the appointment of Shri Kamala Kant Tripathy, IES (1999), as Joint Secretary, Economic Advisory Council to the Prime Minister (EAC-PM), NITI Aayog, from the date of assumption of charge of the post, for a tenure of five years, vide DoPT order dated 21.03.2025.

- The Appointments Committee of the Cabinet has approved the appointment of Shri Raghav Langer, IAS (UD: 2009), as Secretary, National Medical Commission (NMC) (JS level), under the Department of Health & Family Welfare, from the date of assumption of charge of the post, for a combined tenure of seven years up to 03.10.2025, vide DoPT order dated 21.03.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Shri Saket Kumar, IAS (BH: 2009), as Joint Secretary, Department of Commerce, from the date of assumption of charge of the post, for a combined tenure of seven years up to 16.08.2025, or until further orders, whichever is earlier, vide DoPT order dated 21.03.2025.
- Shri Rajiv Gauba, IAS (JH: 1982) has been appointed as Full-Time Member, NITI Aayog, vide Cabinet Secretariat Gazette notification dated 25 March 2025.

**April 2025**

- The Appointments Committee of the Cabinet has approved the appointment of Shri Vumlunmang Vualnam, IAS (MN: 1992), Secretary, Ministry of Civil Aviation, as Secretary, Department of Expenditure, Ministry of Finance, vide DoPT order dated 18.04.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Ms. Anuradha Thakur, IAS (HP: 1994), Additional Secretary, Ministry of Corporate Affairs, as Officer on Special Duty, Department of Economic Affairs, Ministry of Finance, in the rank and pay of Secretary, vide DoPT order dated 18.04.2025. She will take over as Secretary, Department of Economic Affairs, vice Shri Ajay Seth, upon his superannuation on 30.06.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Shri Rajesh Agarwal, IAS (MN: 1994), Additional Secretary, Department of Commerce, Ministry of Commerce & Industry, as Special Secretary, Department of Commerce, vide DoPT order dated 18.04.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Shri Arvind Shrivastava, IAS (KN: 1994), Additional Secretary, Prime Minister's Office, as Secretary, Department of Revenue, Ministry of Finance, vide DoPT order dated 18.04.2025.
- The Appointments Committee of the Cabinet has approved the appointment of Ms. Vinod Kotwal, IP&TA&FS (1994), Member Secretary, NPPA, as Additional Secretary, Ministry of Health & Family Welfare, vide DoPT order dated 18.04.2025.

**May 2025**

- The Appointments Committee of the Cabinet has approved the extension of tenure of Shri Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, on a contract basis for a period of one year beyond 28.06.2025, i.e., up to 28.06.2026, or until further orders, whichever is earlier, on existing terms and conditions, vide DoPT order dated 20.05.2025.
- The Appointments Committee of the Cabinet has approved the appointment of the following, vide DoPT order dated 28 May 2025:
- Ms. Sai Ahlladini Panda, IA&AS (2000), as Member Secretary (JS level), NPPA (National Pharmaceuticals Pricing Authority), Department of Pharmaceuticals, from the date of

assumption of charge of the post, for a tenure of five years.

- Ms. Vrunda Manohar Desai, IRS (IT) (2003), as Additional DGFT, Directorate General of Foreign Trade, Delhi, Department of Commerce, from the date of assumption of charge of the post, for an overall tenure of five years up to 12.04.2027, or until further orders, whichever is earlier, vice Shri Gangadhar Panda, IRS (IT: 1993).

**June 2025**

- The Cabinet Committee has approved the appointment of Dr. V. Kalaiselvan, Senior Principal Scientific Officer, as Secretary-cum-Scientific Director of the IPC, vide DoPT order dated 09.06.2025.
- The Appointments Committee of the Cabinet has approved the re-appointment of Shri Ravi Agrawal, IRS, as Chairman, CBDT, vide DoPT order dated 28.06.2025.

**August 2025**

- Mr. Rajit Punhani, IAS (BH: 1991) has been appointed as CEO, FSSAI, vide DoPT order dated 22 August 2025.
- Shri Satyaprakash TL, IAS (HY: 2002), has been appointed as Joint Secretary, Department of Pharmaceuticals, vide DoPT order dated 13.09.2025.
- Shri Aman Sharma, IPoS (2002), has been appointed as Joint Secretary, Department of Pharmaceuticals, vide DoPT order dated 13.09.2025.

**November 2025**

- Mr. Manoj Joshi, IAS (Kerala: 1998) has been appointed as Secretary, Department of Pharmaceuticals, vide DoPT order dated 21.11.2025.

**REMEMBRANCE OF STALWARTS**

1. Dr. C M Gulati, Editor MIMS
2. Shri Chandrakant I Gandhi, Past National President, IDMA (1985-86)
3. Shri J L Sipahimalani

# VOICE OF THE NATIONAL SECTOR
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