



e-Newsletter

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Materiovigilance Programme of India

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National Coordination Centre - Materiovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare (MoHFW) Government of India

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Medical Device Adverse Event Monitoring Centres (MDMCs)

S. No.	State	MDMC Name & Address	Status
1.	Andhra Pradesh	Pinnacle Hospitals Chinna Gadhili, Hanumanthavaka, Visakhapatnam, Andhra Pradesh-530040	Non-Government
2.	Delhi	Epitome Kidney Urology Institute & Lions Hospital B Block, Ashoka Park Rd, Khizarabad Bhagol, New Friends Colony, New Delhi, Delhi-110025	Non-Government
3.	Gujarat	Haria L G Rotary Hospital Plot No. 363, 1 & 364, Housing Sector, GIDC, Vapi, Gujarat-396195	Non-Government
4.	Karnataka	Sahyadri Narayana Multispeciality Hospital NT Road, Harakere, NT Rd, Harakere, Shivamogga, Karnataka-577202	Non-Government
5.	Karnataka	Rangadore Memorial Hospital 1 st Cross, Shankarapuram, Basavanagudi, Bengaluru Urban Karnataka-560004	Non-Government
6.	Karnataka	Narayana Institute of Cardiac Sciences 258/A, Bommasandra Industrial Area, Hosur Road, Bengaluru, Karnataka-560099	Non-Government
7.	Karnataka	Narayana Multispeciality Hospital HSR Layout Basant Health Centre Building, No-1, 18 th main (Opp. HSR Club), Sector 3, HSR Layout, Bangalore, Karnataka-560102	Non-Government
8.	Karnataka	Narayana Health-Mazumdar Shaw Medical Centre 258/A, Bommasandra Industrial Area, Hosur Road, Anekal Taluk, Bangalore, Karnataka-560099	Non-Government
9.	Karnataka	Shri B.M Patil Medical College, Hospital & Research Centre Solapur Rd, Bangaramma Sajjan Campus, Vijayapura, Karnataka- 586103	Non-Government
10.	Karnataka	Institute of Nephro-Urology Victoria Hospital Campus, Alur Venkata Rao Rd, New Tharagupet, Bengaluru, Karnataka-560002	Government
11.	Karnataka	Sri Shankara Cancer Hospital and Research Centre 1 st Cross, Shankara Matt Premises, Shankarapuram, Basavanagudi, Bengaluru, Karnataka-560004	Non-Government
12.	Karnataka	Chikkaballapur Institute of Medical Science New District Hospital Campus, Chikkaballapur, MG Road, Karnataka-562101	Government

Medical Device Adverse Event Monitoring Centres (MDMCs)

13.	Karnataka	Arihant Hospital Unit of Dixit Healthcare Private Limited Unit of Dixit Healthcare Private Limited C-Square CTS No. 10632, A1/B, Nehru Nagar, Belagavi, Karnataka-590010	Non-Government
14.	Karnataka	Shri Atal Bihari Vajpayee Medical College and Research Institute 1, Lady Curzon Rd, Shivaji Nagar, Bengaluru, Karnataka -560001	Government
15.	Karnataka	Mandya Institute of Medical Sciences Mandya, Karnataka-571403	Government
16.	Karnataka	Gadag Institute of Medical Sciences 9JH2+FR4, SH 6, Malasamudra, Karnataka-582103	Government
17.	Karnataka	Koppal Institute of Medical Sciences 952M, Gangavathi Rd, Kiddidal Gate, Bhagyanagar, Karnataka- 583231	Government
18.	Karnataka	Sagar Hospital Shavige Malleshwara Hills, DSI, Banashankari, Behind DSI Campus, Kumaraswamy Layout, Bengaluru, Karnataka-560078	Non-Government
19.	Karnataka	Bangalore Baptist Hospital Bellary Road, Hebbal, Bangalore-560024	Non-Government
20.	Karnataka	Sagar Hospitals No.44/54 30th Cross, Extension, Tilak Nagar, Jayanagar, Bengaluru, Karnataka-560041	Non-Government
21.	Karnataka	Yenepoya Speciality Hospital KSR Road, Opp Bishop's House, Kodailbail, Mangaluru, Karnataka-575003	Non-Government
22.	Karnataka	Apollo BGS Hospital Adhichurchangiri Road, Kuvenpunaga, Mysore, Karnataka-570023	Non-Government
23.	Kerala	Government Medical College and Hospital HMT Colony P.O Kalamassery Cochin, Kerala-683503	Government
24.	Kerala	Sun Medical & Research Centre Bus Stand, Near Sakthan Thampuran, Sakthan Thampuran Nagar, Kannamkulangara, Thrissur, Kerala-680001	Non-Government
25.	Kerala	Taluk Hospital Attingal, Valiyakunnu, Kizhuvilam (P O) Thiruvananthapuram, Kerala-695104	Government
26.	Kerala	Rajagiri Hospital Chunangamvely Edathala PO, Aluva, Kerala-683112	Non-Government
27.	Kerala	Community Health Centre Irikkur PO, Kerala-670593	Government

28.	Kerala	Aster Malabar Institute of Medical Sciences Private Limited Chala East, Kannur, Kerala-670621	Non-Government
29.	Kerala	Government Taluk Hospital Perambra, Kerala-673525	Government
30.	Kerala	Ananthapuri Hospitals & Research Institute Chackai, NH Bypass, Thiruvananthapuram, Kerala-695024	Non-Government
31.	Kerala	Star Hospital N H Bypass Junction, Near Thondayad, Kozhikode, Kerala-673017	Non-Government
32.	Kerala	Taluk Hospital Santhivila, Nemom, Thiruvananthapuram, Kerala-695020	Government
33.	Kerala	Avtis Super Specialty Hospitals Private Limited Building No. XX/882, Opposite Japamalarani Church, Thrissur- Pollachi Main Road, Nemmara, Palakkad, Kerala-678508	Non-Government
34.	Kerala	Aster Medcity Kuttisahib Road, Cheranelloor, South Chittoor, Kerala-682027	Non-Government
35.	Kerala	Rama Rao Memorial Taluk Hospital Nedungolam (PO) Paravur, Kollam, Kerala-691334	Government
36.	Kerala	SP Fort Hospital Anakottil St, West Fort, Pazhavangadi, Thiruvananthapuram, Kerala-695023	Non-Government
37.	Kerala	Apollo Adlux Hospital Near Adlux Convention Center Cable Junction Ernakulam District, National Highway 47 Karukutty, Angamaly, Kerala-683576	Non-Government
38.	Kerala	Dr. Moopen's Medical College Wayanad, Kerala-673577	Non-Government
39.	Kerala	Taluk Headquarters Hospital Paravur Main Road, Near Private Bus Stand, North Paravur, Kerala-683513	Government
40.	Kerala	Malabar Institute of Medical Sciences Pvt. Ltd Kottakkal, Changuvetty, Malappuram, Kerala-676503	Non-Government
41.	Kerala	Government Maharajas Taluk Hospital Moulana Azad Rd, Karuvelipady, Thoppumpady, Kochi, Kerala-682005	Government
42.	Kerala	Government Women & Children's Hospital Jew Town Rd, opp. to Police Station, Mattancherry, Kochi, Kerala-682002	Government

Medical Device Adverse Event Monitoring Centres (MDMCs)

43.	Kerala	Mar Augustine Golden Jubilee Hospital Mookkannoor, Kerala-683577	Non-Government
44.	Kerala	Government Taluk Hospital Urath, Kuttiady, Kerala-673508	Government
45.	Kerala	Taluk Hospital Kadakkal, Kollam, Kerala-691536	Government
46.	Kerala	Taluk Hospital Thuravoor, Thekku, Kerala-688532	Government
47.	Kerala	Government Medical College Mavoor Rd, Kozhikode, Kerala-673008	Government
48.	Kerala	Taluk Head Quarters Hospital Koyilandy, Kozhikode, Kerala-673305	Government
49.	Kerala	Taluk Hospital Pazhayangadi, (PO)Kannur, Kerala-670303	Government
50.	Kerala	Taluk Head Quarters Hospital Perumbavoor, P.O, Kerala-683542	Government
51.	Kerala	District Hospital Thodupuzha, Kerala-685585	Government
52.	Kerala	Taluk Head Quarters Hospital Adimaci P.O, Idukki, Kerala-685561	Government
53.	Kerala	Taluk Head Quarters Hospital Nedumkandam, Idukki, Kerala-685553	Government
54.	Kerala	Government Medical College District Hospital Idukki, Kerala-685502	Government
55.	Kerala	Taluk Headquarters Hospital Road Azutha, Peermade, P.O, Idukki, Kerala-685531	Government
56.	Kerala	Taluk Head Quarters Hospital Kothamangalam, Ernakulam, District, Kerala-686666	Government
57.	Kerala	Kinder Women's Hospital & Fertility Centre Private Limited Near N.H-66, Maruthorvattom Temple Road, Cherthala, Kerala-688539	Non-Government
58.	Kerala	Taluk Hospital Kundara, Kanjirakodu, Malavana, Kundara, Kollam, Kerala-691501	Government
59.	Kerala	KIMS Health P.B No.1 Anayara P.O, Kerala -695029	Non-Government
60.	Kerala	Government Medical College Kollam, Paripally, Kerala -691574	Government

61.	Kerala	Regional Cancer Centre Thiruvananthapuram, Medical College Kumarapuram Rd, Medical College Campus, Chalakkuzhi, Thiruvananthapuram, Kerala-695011	Government
62.	Kerala	Mar Sleevea Medicity Cherpunkal - Kozhuvanal Road, Cherpunkal, Kerala-686584	Non-Government
63.	Kerala	Taluk Hospital Kattappana, Thovarayar, Kerala-685511	Government
64.	Kerala	EMS Memorial Co-Operative Hospital and Research Centre, Panambi, Perintalmanna, Kerala-679322	Non-Government
65.	Kerala	Dhanlakshmi Hospitals Private Limited Kannomthumchal Road, Kannur, Kerala-670002	Non-Government
66.	Kerala	LISIE Hospital Ernakulam, Kochi, Kerala-682018	Non-Government
67.	Kerala	Malabar Cancer Centre Thalassery, Kodyeri, Muzhikkara - MCC Rd, Illathaazha, Thalassery, Kerala-670103	Government
68.	Kerala	Nyle Institute of Medical Science Private Limited Thrissur - Kaiparambu Road, Kaiparambu, Kerala-680546	Non-Government
69.	Kerala	Little Flower Hospital and Research Centre SH 1, Angamaly, Kerala-683572	Non-Government
70.	Kerala	Aster Mother Hospital Vazhakkad Road, Ugrapuram P.O, Areekode Malappuram, Kerala-673639	Non-Government
71.	Kerala	M.A.J Hospital Market Rd, Edappally, Kochi, Kerala-682024	Trust
72.	Kerala	Lourdes Hospital Road Near Ernakulam Town Railway Station Pachalam PO, Kochi, Ernakulam, Kerala-682012	Non-Government
73.	Kerala	Taluk Hospital Madapuram, Kerala-673504	Government
74.	Madhya Pradesh	Atal Bihari Vajpayee Government, Medical College & Hospital Vidisha, Sanchi Road Madhya Pradesh-464001	Government
75.	Maharashtra	Dr. L H Hiranandani Hospital Hillside Rd, Hiranandani Gardens, Ramabai Ambedkar Nagar, Powai, Mumbai, Maharashtra-400076	Non-Government
76.	Maharashtra	Global Hospital Super Speciality & Transplant Centre 35, Dr Ernest Borges Rd, Opp. Shirodkar High School, Parel East, Parel, Mumbai, Maharashtra-400012	Non-Government

Medical Device Adverse Event Monitoring Centres (MDMCs)

77.	Maharashtra	Ashoka Medcover Hospital Indira Nagar, Wadala Road, Nashik, Maharashtra-422009	Non-Government
78.	Puducherry	ESIC Hospital Victory Research Institute Dhoordarsan, VCRC Rd, Gorimedu, Puducherry-605006	Government
79.	Puducherry	Indira Gandhi Medical College and Research Institute Kathirkamam, Puducherry-605009	Non-Government
80.	Puducherry	ESI Dispensary Gurimedu, Puducherry-605110	Government
81.	Punjab	Guru Nanak Dev Super Speciality Hospital Goindwal, Sahib Road, Tarn Taran Sahib, Punjab-143401	Non-Government
82.	Rajasthan	Solanki Hospital 10, Alwar HO, Ram Kutir, Ashoka Circle, Rajasthan-301001	Non-Government
83.	Tamil Nadu	Velammal Medical College Hospital and Research Institute Velammal Village, Madurai-Tutorin Ring Road, Anuppanadi-Madurai, Tamil Nadu-625009	Non-Government
84.	Tamil Nadu	Gleneagles Global Health City No:439, Cheran Nagar, Perumbakkam, Chennai, Tamil Nadu-600100	Non-Government
85.	Tamil Nadu	Cancer Institute (WIA) No.38, Sardar Patel Road, Adyar, Chennai Tamil Nadu-600020	Non-Government
86.	Tamil Nadu	Adhiparasakthi Hospital & Research Institute Melmaruvathur, Kancheepuram District TamilNadu-603319	Non-Government
87.	Tamil Nadu	Apollo Speciality Hospital Lake View Road, K.K. Nagar, Madurai, Tamil Nadu-625020	Non-Government
88.	Tamil Nadu	COSH Multispeciality Hospital 9, Air Force Station Rd, Duraisamy Nagar, East Tambaram, Tambaram, Chennai, Tamil Nadu-600059	Non-Government
89.	Tamil Nadu	G. Kuppuswamy Naidu Memorial Hospital PB No-6327, Pappan Aicken Palayam, Coimbatore, Tamil Nadu-641037	Non-Government
90.	Tamil Nadu	Ganga Medical Centre & Hospitals 313, Mettupalayam Road, Coimbatore, Tamil Nadu-641043	Non-Government
91.	Tamil Nadu	Dhanalakshmi Srinivasan Medical College & Hospital Siruvachur, Perambalur, Tamil Nadu-621113	Non-Government
92.	Tamil Nadu	Medway Hospital Block No.4 Pc7, Nolambur, Bharathi Salai, Mogappair West, Ambattur Industrial Estate, Chennai, Tamil Nadu-600037	Non-Government

93.	Tamil Nadu	Sundaram Medical Foundation Dr. Rangarajan Memorial Hospital 9C, 4 th Ave, AH Block, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu-600040	Non-Government
94.	Tamil Nadu	Sree Renga Hospital No .12 Varada Reddy Street, Vedachalam Nagar, Chengalpattu, Tamil Nadu-603001	Non-Government
95.	Tamil Nadu	Government Hospital of Thorasic Medicine 77, Chennai - Theni Highway Sanatorium, Kadaperi, Chennai, Tamil Nadu-600047	Government
96.	Tamil Nadu	Hannah Joseph Hospital Limited Madurai- Tuticorin Ring Road, Chinthamani, Near Tollgate, Madurai, Tamil Nadu-625009	Non-Government
97.	Tamil Nadu	SRM Medical College Hospital and Research Centre Mahatma Gandhi Rd, Potheri, SRM Nagar, Kattankulathur, Tamil Nadu-603211	Non-Government
98.	Tamil Nadu	Medway Hospitals 2, 26, 1 st Main Rd, United India Colony, Kodambakkam, Chennai, Tamil Nadu-600024	Non-Government
99.	Tamil Nadu	Sri Narayani Hospital and Research Centre Thirumalaikodi, Vellore, Tamil Nadu-632055	Non-Government
100.	Tamil Nadu	Apollo KH Hospital Nh48, Chennai-Bangalore Highway, Melvisharam Ranipet, Kanchipuram - Vellore Rd, Melvisharam, Tamil Nadu-632509	Non-Government
101.	Tamil Nadu	MIOT Hospitals Private Limited 4/112, Mount Poonamalle Road, Chennai, Tamil Nadu-600089	Non-Government
102.	Tamil Nadu	Scudder Memorial Hospital Kellys Road, Navalpur, Ranipet, Walajapet, Tamil Nadu-632401	Non-Government
103.	Tamil Nadu	KMC Speciality Hospitals No.6 Royal Road Cantonment Trichy Tamil Nadu-620001	Non-Government
104.	Tamil Nadu	Ortho-One Orthopaedic Speciality Centre 657, Trichy Rd, Kallimadai, Singanallur, Tamil Nadu-641005	Non-Government
105.	Tamil Nadu	Rela Hospital - Multispeciality Hospital 7, CLC Works Rd, Nagappa Nagar, Chromepet, Chennai, Tamil Nadu-600044	Non-Government
106.	Uttar Pradesh	Prakash Hospital Private Limited D-12, 12A,12B, next to ISKCON Mandir, Block D, Sector 33, Noida, Uttar Pradesh-201301	Non-Government
107.	Uttarakhand	Government Doon Medical College Hospital 829R, New Rd, Race Course, Dehradun, Uttarakhand-248001	Government

Training & Education

Training Programme on ISO standards for IPC officials

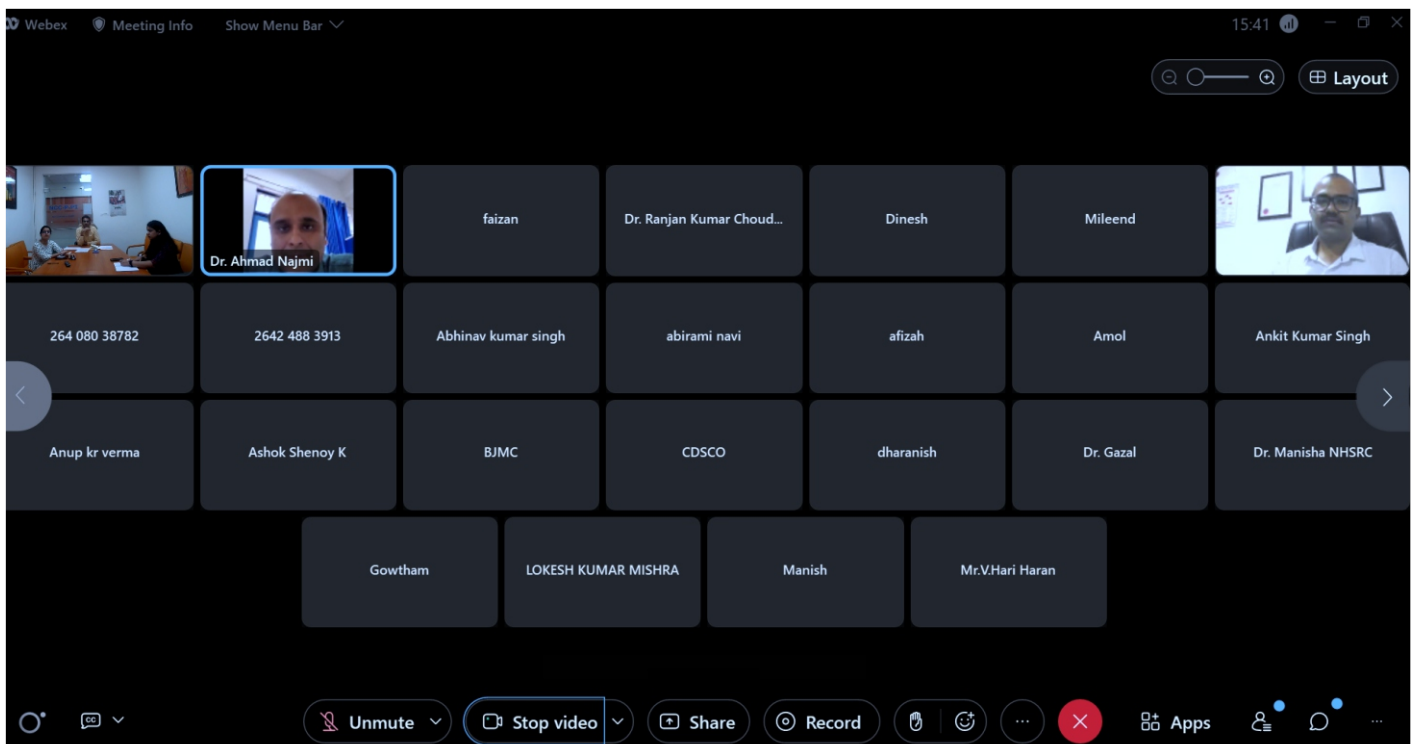
National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) organized two days training programme on "ISO 9001:2015, ISO 13485:2015 and ISO:14971 Internal Auditor Training on Quality Management System" on April 19-20, 2023, May 8-9, 2023 and May 17-18, 2023 respectively. Ms. Vareena Raina, Medical Device Auditor and Trainer, TUV South Asia made aware the IPC officials regarding the ISO standards. She has also conducted various group exercises for the benefit of participants.



Webinar on “Orthopedics implants- Clinical updates and safety” for MDMCs



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in collaboration with AIIMS, Bhopal conducted a webinar on “Orthopedics implants- Clinical updates and safety” on April 20, 2023. Coordinators/deputy coordinators/Materiovigilance associates from the various medical device adverse event monitoring centres (MDMCs) participated in this webinar and enhanced their knowledge on the safety of orthopaedic implants. Dr. Dinesh Chidambaram, Consultant Trauma & Arthroscopy Surgeon, Dr. M. Sudhakaran, Consultant Orthopaedic Spine Surgeon and Spine Endoscopist and Dr. C Karthikeyan, Consultant Orthopaedic Surgeon from Royal Care Super Specialty Hospital, Coimbatore were the speakers for the said webinar.



Webinar on “Monitoring the safety of Dental Implants” for MDMCs



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a webinar on “Monitoring the safety of Dental Implants” on April 27, 2023. Coordinators/Deputy Coordinators/Materiovigilance associates from the various MDMCs participated in this webinar and enhanced their knowledge on the safety of dental implants. In total 100 participants were participated in the said webinar. Dr. Parvesh Mehra, Director Professor & Head, Oral Maxillofacial Surgery, Lady Hardinge Medical College, New Delhi and Dr. Shruthi Acharya, Associate Professor, Manipal College of Dental Sciences, Manipal were the speakers for the said webinar.

An Advanced Level Training Programme on Pharmacovigilance



An Advanced Level Training Programme on Pharmacovigilance organized by Madras Medical College, Chennai on May 10, 2023. Dr. V Kalaiselvan, Senior Principal Scientific Officer, IPC presented a session virtually on “Recent Advances in Materiovigilance Programme of India” in the said training programme.

Materiovigilance Conference: India Pharma and India Medical Device 2023



Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in association with the Federation of Indian Chambers of Commerce & Industry (FICCI) organized 8th Annual Conference on May 26-27, 2023 at The Ashok, New Delhi. In the conference, NCC-MvPI, IPC conducted a materiovigilance conference to sensitize the medical device stakeholders about the Materiovigilance programme and tools for reporting medical device adverse events.

Dr. Kavita Gulati, Director Professor, Vallabhbhai Patel Chest Institute, New Delhi and Ms. Nikita Mishra, Materiovigilance Associate, MvPI were the speakers for the conference. MvPI team also set up a stall to showcase the resource material of IPC.



An Annual Conference of Society of Pharmacovigilance



An annual conference of Society of pharmacovigilance conducting by AIIMS Rishikesh on May 11-12, 2023. The objective of the conference intends to provide a platform for discussion about different issues pertaining to safety of medicinal products ranging from quality of pharmaceuticals to pooled analysis of safety data from clinical investigations. Dr. V Kalaiselvan, Senior Principal Scientific Officer, IPC presented a session virtually on "Overview of Materiovigilance programme" in the said conference.

DIA India 10th Pharmacovigilance Conference

DIA organized two days conference on "DIA India 10th Pharmacovigilance Conference PV 2023– Re-designing and Transforming PV for Augmenting Patient Safety" on May 25-26, 2023 at Mumbai. Dr. Shatrúnajay Shukla, Scientific Assistant, IPC presented a session entitled "Regulator's view-point in Positioning Medical Device Vigilance in India in the changing Regulatory Landscape" in the said conference.



Field Activities

Workshop on Indian Medical Devices Rules, 2017



Mr. V. Hari Haran, Senior Materiovigilance Associate, MvPI participated in the hybrid mode workshop on Indian Medical Devices Rules, 2017 on June 09-10, 2023 organized by AMTZ, Visakhapatnam and explained about the reporting tools of MvPI to participants from MedTech Industries, Startups and also attended a meeting with Mr. Nitturi Naresh Kumar from AMTZ for encouraging Biomedical engineering students to participate in the MvPI internship offered by IPC with support of Professors from Biomedical engineering colleges in Bengaluru.

Training programme for derecognized MDMCs



After de-recognition of Kidwai Memorial Institute of Oncology (KMIO) as an MDMC under MvPI, KMIO administration taken efforts to organize a meeting jointly with RTC-MvPI, NIMHANS on June 14, 2023 along with Pharmacovigilance committee members for the strengthening of Materiovigilance & Pharmacovigilance system at auditorium Infosys OPD building KMIO.

Training programme for Nursing Superintendent



Dr. Nalini Mishra, Materiovigilance Associate, MvPI conducted an awareness programme for all Assistant Nursing Superintendents of AIIMS, Rishikesh of all departments on 'Importance of reporting of medical device adverse events' on June 16 and 30, 2023. In total, 44 participants participated in the said training programme.

Meeting with Drugs Controller, Odisha, Bhubaneshwar

Ms. Shri Pada Behera, Materiovigilance Associate, MvPI conducted a meeting with Drugs Controller, Odisha, Bhubaneshwar on Materiovigilance Programme on 18 May, 2023. She made aware the delegates about identification, collection, reporting, estimating the undesirable occurrence and the possible management of adverse events associated with the use of medical devices under MvPI. Meeting members also participated in the discussion for getting feedback/reporting from user's end on any adverse event.



CME on Pharmacovigilance and Materiovigilance Programme of India

Amar Shaheed Baba Ajit Singh Jujhar Singh Memorial College of Pharmacy, Bela (Punjab) conducted continuation of education (CME) on Pharmacovigilance and Materiovigilance Programme of India on May 22, 2023. There were around 150 staff members and students who attended the programme. Dr. Bikash Medhi, Professor, PGIMER, Chandigarh explained about the need and necessity of the programme in the hospitals and research institutes. Furthermore, Dr. Bikash Medhi emphasizes on the Drugs and MDR rule 2017 provided the different classifications of the drugs and medical device used in the country. Several practical examples of the cases were made all the faculties and students to understand well and simple.



Memorandum of Understanding (MoU)

Memorandum of Understanding (MoU)



Indian Pharmacopoeia Commission, Ghaziabad has signed a Memorandum of Understanding (MoU) with National Accreditation Board of Hospitals and Healthcare Providers (NABH) to promote monitoring and reporting of Adverse Drug Reactions (ADRs) and Medical Device associated Adverse Events (MDAEs) by NABH accredited Hospitals to PvPI & MvPI respectively.



Medical Device Updates

F. No. 29/Misc/03/2022-DC (94)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare

FDA Bhawan, New Delhi
Dated the April, 2023

CIRCULAR


12 APR 2023

Subject: Licensing regime of Class C & D non-notified medical devices which are currently under mandatory registration, as per GSR 102(E) dated 11.02.2020, under Medical Devices Rules 2017, w.e.f from 01.10.2023 - Regarding.

As you are aware, that the Class C and D non-notified Medical Devices which are currently under mandatory registration, will be under licensing regime w.e.f 01.10.2023, as per GSR 102(E) dated 11.02.2020.

It is pertinent to mention that, as per Medical Devices Rules (MDR) 2017, for grant of manufacturing license of Class C and D medical devices, the inspection needs to be carried out within 60 days from the date of application by the Medical Devices Officers (MDO) of Central Licensing Authority (CLA), to ensure the compliance with Fifth Schedule of MDR 2017.

In order to have smooth transition from mandatory registration to licensing regime, it is suggested that, the manufacturers/importers may apply for grant of manufacturing/import license with all requisite documents and fees as per MDR 2017, through www.cdscsonline.gov.in portal. The application received will be processed proactively, so that, license can be issued within the stipulated time line in order to avoid any disruption of the supply chain of such medical devices and access to the patients.


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To
All Stakeholders/Associations.

Copy to:
1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.

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Licensing regime of Class C & D non-notified medical devices which are currently under mandatory registration, as per GSR 102(E) dated 11.02.20, under Medical Device Rules 2017, w.e.f from 01.10.2023.

File No. 29/Misc/3/2017-DC (288)
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Devices Division)

Date: 03 APR 2023

NOTICE

Subject: List of Notified Bodies registered with CDSCO under MDR, 2017- regarding

As you are aware that Medical Devices Rules, 2017, has already been published vide G.S.R. 78 (E) dated 31.01.2017 under Drugs and Cosmetic Act to regulate the manufacture, import, sale and distribution of the medical devices and said rules are effective from 01.01.2018.

The notified bodies registered with CDSCO under provisions Medical Devices Rules, 2017 to carry out audit of manufacturing site under the provisions of said rules. In this connection, following Notified Bodies have been registered with CDSCO:

1. M/s Intertek India Pvt. Ltd.,
E-20, Block B1, Mohan Cooperative, Industrial Area E-20,
Block B1, Mohan Cooperative, Industrial Area New Delhi (India) - 110044
Telephone No.: 011-41595475, 9310412823 Fax: 011-41595460
E-Mail: kamal.gupta@intertek.com
Registration Certificate No. RC/NB-000001

2. M/s TUV Rheinland India Pvt. Ltd.,
82/A West Wing, 3rd Main Road 82/A West Wing,
3rd Main Road Electronic City (India) - 560100
Telephone No.: 080-46498030 Fax: 080 4649 8042
E-Mail: gunuprasad.nc@ind.tuv.com
Registration Certificate No. RC/NB-000002

3. M/s TUV Sud South Asia Pvt. Ltd.,
TUV SUD House, Off Saki Vihar Road, Saki Naka,
Andheri (East), Mumbai-400072,
Telephone No.: 022-49035508 Fax: 022-49035508
E-Mail: info@tuv-sud.in
Registration Certificate No. RC/NB-000003

4. M/s, Dny GI Business Assurance India Private Limited
Equinox Business Park, Tower 3, 6th Floor, BKC, LBS Road,
Kurla West, Mumbai-400070 (India).

Page 1 of 3

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CDSCO has published the List of Notified Bodies registered with CDSCO under MDR, 2017.

Safety Alerts

NCC-MvPI, IPC has observed an adverse event report of Ralstonia Mannitolilytica Infection associated with the use of Trans Catheter Pulmonary Valve which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Trans Catheter Pulmonary Valve	Ralstonia Mannitolilytica Infection

NOTE

You are requested to closely monitor the adverse events of these devices at your respective monitoring centre. If these devices are being used at your hospital. Kindly report all the suspected adverse events in medical device adverse event, if any using reporting form after the use of these devices to NCC-MvPI, IPC via e-mail: shatrunjay.ipc@gov.in or mvpi-ipc@gov.in.

IMPORTANT MESSAGE

The content of this safety alert is highly confidential. It is strictly forbidden to share any part of the message with any third party/vendor or on public platforms such as social media, local newspapers/posters etc., without a written consent of the sender. Your support in this regard is highly solicited.



Recommendation to Central Drugs Standard Control Organization (CDSCO)

1

NCC-MvPI sent a recommendation to CDSCO on **"Stent Couldn't Cross the Lesion Site"** associated with **"Drug Eluting Stent"** for information and necessary actions at their end.

2

NCC-MvPI sent a recommendation to CDSCO on **"Reading errors"** associated with **"Pregnancy Test Kit"** for information and necessary actions at their end.

3

NCC-MvPI sent a recommendation to CDSCO on **"Reading errors/BP Cuff Leakage/Inflation Bulb Damage/Pressure Holding Issue"** associated with **"Blood Pressure Monitor"** for information and necessary actions at their end.

Feedback on MvPI

Materiovigilance Programme of India (MvPI) has taken the greatest initiation in the field of materiovigilance and empowers all healthcare professionals for the safety surveillance of medical devices. MvPI has increased the awareness among healthcare professionals for reporting medical device adverse events and ensuring patient safety. I appreciate the efforts for their magnificent performance. I wish them good luck for their future endeavour towards patient safety.



Dr. C Deepa Latha

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The Materiovigilance Programme of India (MvPI) is a commendable initiative of Indian Pharmacopoeia Commission, Ghaziabad, exemplifying an unwavering commitment to patient safety and quality healthcare. By ensuring medical device safety, it inspires hope for patients and healthcare providers. By promoting transparency, accountability, and continuous improvement, it encourages responsible innovation. MvPI stands as evidence of the power of collective action in promoting safer healthcare practices and inspires healthcare systems nationwide.

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We have started a journey of Materiovigilance, for saving patient's lives