



e-Newsletter

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A central hexagonal frame with a purple and orange border contains a faded image of a medical professional wearing a white cap, glasses, and a face mask, surrounded by various medical equipment and wires. The text 'Materiovigilance Programme of India' is overlaid on this image in a bold, pink font.

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

Contents

3

Medical Device Adverse Event Monitoring Centres

5

Training & Educations

10

MvPI Participation in Indian Pharma Expo

11

Government Notification on MvPI

12

Medical Device Update

13

Safety Alerts

14

Publication

15

Recommendations to Central Drugs Standard Control Organization



NEW MDMCs

Medical Device Adverse Event Monitoring Centres (MDMCs)

All India Institute of Medical Science,
Raipur Tatibandh,
GE Road, Raipur,
Chhattisgarh

Government

Coordinator : Dr. Pugazhenthana. T
Deputy Coordinator : Mr. Sumedh M Lemte
E-mail ID : drpugal@aiimsraipur.edu.in

Pt. B D Sharma
Postgraduate
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Coordinator : Dr. Jyoti Kaushal
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Narayana
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Hospital Complex
Greenland
Restaurant Tularam
Bafna, Amingaon,
Guwahati, Assam

Non-Government

Coordinator : Dr. Hirak Jyoti Das
Deputy Coordinator : Mr. Bikram Sil
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Ujala Cygnus
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Kaladhungi Road,
Near Gas Godam,
Tiraha, Kusumkhara,
Haldwani,
Uttarakhand

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Lady Hardinge
Medical College,
DIZ Area,
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New Delhi

Government

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Divisional Railway
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Southern Railway,
Trivandrum, Kerala

Government

Coordinator : Dr. Livina Narendra
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Mahavir Heart
Institute, Mahavir
Health Campus,
Opp.Vanita Vishram
Ground, Athwa
Gate, Surat,
Gujarat

Non-Government

Coordinator : Mr. Ashish K Jadav
Deputy Coordinator : Dr. Atul Abhyankar
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Indira Gandhi
Government
General Hospital &
Post Graduate
Institute, Victor
Simonel, St, White
Town, Puducherry

Government

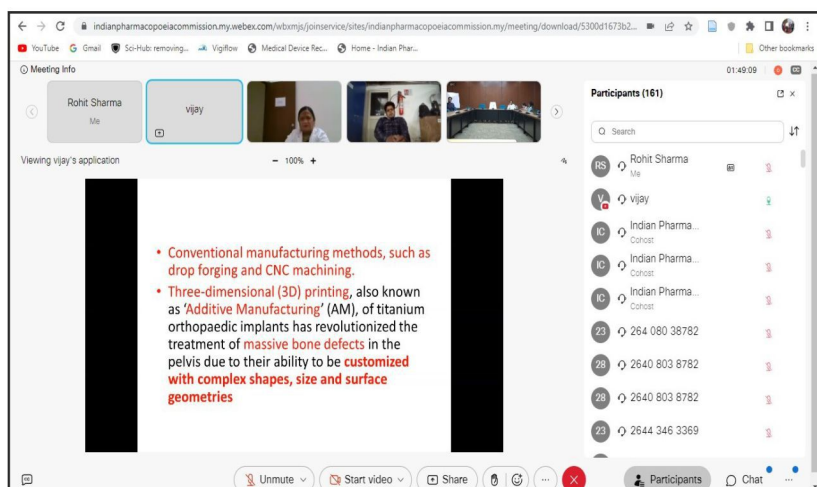
Coordinator : Dr. Edward
Deputy Coordinator : Dr. K.G. Rani
E-mail ID : msg@py.gov.in



Delhi Pharmaceutical Sciences and Research University (DPSRU), Pushp Vihar, New Delhi organized 2nd Annual Conference of Delhi Pharmacological Society DPSCON-2023 entitled "Advances and Current Trends in Pharmacology" on March 01, 2023. Ms. Nikita Mishra, Materiovigilance Associate, MvPI & Mr. Surya Pratap Yadav, Junior Materiovigilance Associate, MvPI participated in the annual conference and enhanced their knowledge.

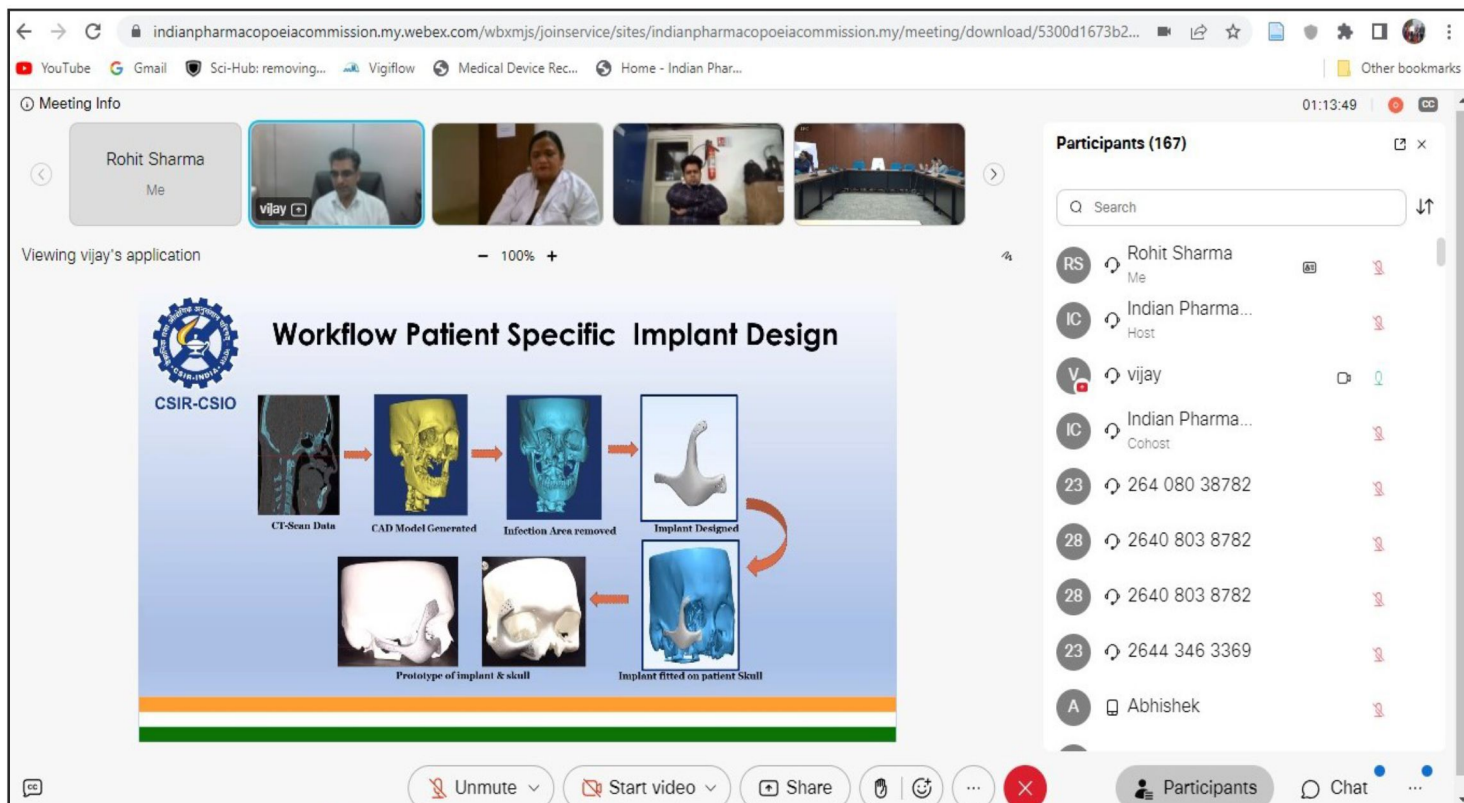
MvPI team also delivered the oral presentation on "Importance of adverse event reporting associated with wearables medical devices" and "Role of Artificial intelligence (AI) in the safety of patient" in the conference. The idea behind presenting in the conference is to aware the audience about the safe use of medical devices and promote patient safety. Members of Delhi Pharmacological Society also understands the importance of medical device vigilance practices and said that it is equally important as drug vigilance practices in India. Members decided to include MvPI trainings on both the nation-wide programmes (Pharmacovigilance & Materiovigilance Programme of India) for the upcoming annual conference of Delhi Pharmacological Society.





National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in association with National Health System Resource Centre, New Delhi conducted a webinar on "Monitoring the safety of customized Implants" on March 14, 2023. Coordinators from the different MDMCs and MvPI associates participated in the webinar and enhanced their knowledge on the safety of customized implants. In total, 200 participants participated in the said webinar.

Dr. Vijay Kumar Meena, Senior Scientist, Biomedical Instrumentation, Council of Scientific & Industrial Research - Central Scientific Instruments Organisation (CSIR-CSIO), Chandigarh presented a session on "Metal Additive manufacturing for Biomedical Implants" and Dr. Vijay Kumar Jain, Professor & Chief Medical Officer, Ram Manohar Lohia Hospital, New Delhi presented a session on "Role of customized implants in Orthopaedics". Eminent speakers also resolved the queries raised by the participants in the webinar.





National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in collaboration with Sharda University organized a national conference on "Scope & Research Opportunities for the Pharmacy professionals in Pharmacovigilance & Materiovigilance from March 17-18, 2023. The objective of this national conference is to sensitize and develop the basic understanding of pharmacy professionals, students on the safety surveillance of medical products. Dr. V Kalaiselvan, Senior Principal Scientific, Officer, IPC, Ghaziabad presented a session on "Materiovigilance Overview". Dr. Shatrúnajay Shukla, Ms. Nikita Mishra, Ms. Numra Saifi & Mr. Sandeep Mewada (Trainee) participated and presented the poster in the said conference. MvPI team also delivered the oral presentation in the national conference and sensitized the pharmacy professionals about the safety of medical devices.



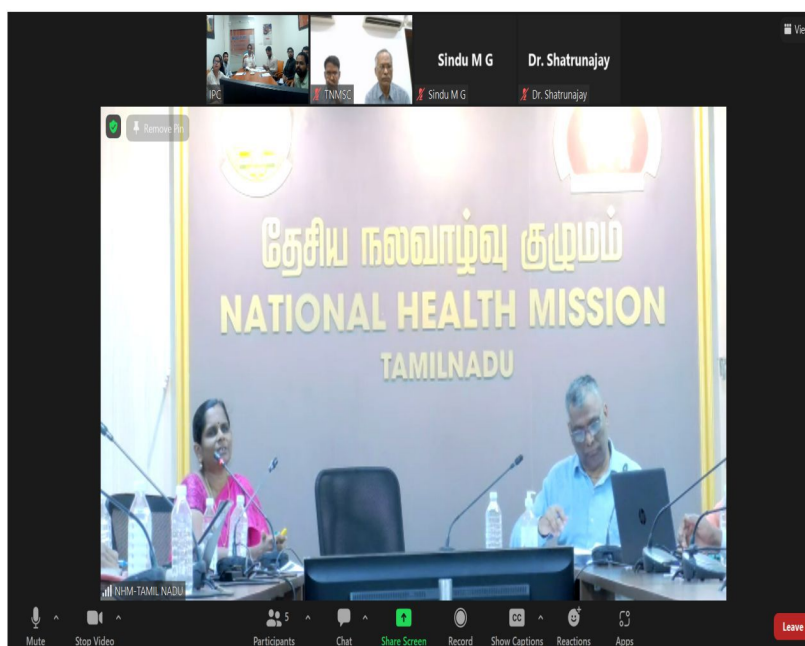
In the conference, MvPI team also chaired one session of Dr. Sudhir Chandra Sarangi, Professor from AIIMS, New Delhi on "Research in Materiovigilance Academic Prospective". MvPI team received the 1st position in the conference.



Santosh Medical College, Noida conducted a workshop on "Pharmacovigilance Sensitization programme and Health & Science Symposium" on March 28, 2023. Ms. Krishna, Jr. Materiovigilance Associate, MvPI participated in the workshop and enhanced the knowledge of healthcare professionals and students on the safety surveillance of medical devices. In total, 117 participants participated in the said workshop and developed their basic understanding on the tools for reporting medical device adverse events in Materiovigilance programme.

BVM College of Pharmacy, Gwalior, Madhya Pradesh organized 2nd National Seminar on "Safety Surveillance System for Medical Products" on March 25, 2023. Mr. Maneesh Soni, Sr. Materiovigilance Associate, MvPI presented a session on "Pharmacovigilance and Risk Management Strategies" in the seminar. In total, 200 participants including faculty members and pharmacy students participated in the said webinar and enhanced their knowledge.





National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a training programme on "Implementation of Materiovigilance Program of India in State of Tamil Nadu" on March 31, 2023. Members from National Health Mission, Tamil Nadu & Tamil Nadu Medical Supply Cooperation Limited participated in the said training programme and developed their basic understanding on the programme objectives, medical device regulation, how, what and where to report medical device adverse events. Meeting experts also discussed the barriers to implement patient safety systems.

om Meeting You are viewing Sindu M G's screen View Options

TNMSC Sindu M G Dr. Shatrunajay

NH-M-TAMIL NADU IPC TNMSC

BARRIERS TO IMPLEMENTATION

Top 7 barriers to implementing patient safety systems

- Competing priorities for scarce resources in a system where patient safety is not considered a top priority
- Lack of resources : Inadequate staffing and work overloads
- Availability and cost of patient safety technology
- Resistance to change (the assumption that providers are already providing safe care)
- Culture of blame (Current healthcare culture is punitive in nature)
- Lack of senior leadership understanding of and involvement with patient safety issues
- Culture of healthcare workforce perceptions, attitude and behaviours of error cover up

Thanks

mute Stop Video Participants Chat Share Screen Record Hide Captions Reactions Apps Leave

29°C Haze Search 13:13 29-03-2023



Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru has conducted a value-added course on Basics to Advance in Materiovigilance for the Post Graduate students on March 02, 2023. In total, 110 students attended the event in which topics on Classification, Concepts, Terminologies, tools for reporting adverse events, product life cycle & regulatory requirements in Materiovigilance were presented followed by a question-and-answer session.

Dr. A. Pramod Kumar, Ramaiah University of Applied Sciences, Bangalore and Mrs. Ritu Jain, L&T Technology Services, Bangalore were the speakers for the event.

An awareness program was conducted at Sri Lakshmi Narayan Medical College & Research Institute, Puducherry on February 11, 2023 by Mr. V Hari Haran, Senior Materiovigilance Associate, MvPI. The objective of the awareness programme is to enhance the reporting culture and improve the performance of underreporting centres. Mr. V Hari Haran also had a discussion with hospital administrators about the importance of reporting incidents to the MvPI.



JSS College of Pharmacy, Mysuru organised '52 Annual Conference of Indian Pharmacological Society' from February 23 -25, 2023. IPC also set up a stall to promote IPC products and services. Mr. V Hari Haran participated in the conference and sensitized stakeholders and healthcare professionals to participate in MvPI & report the incidents related to medical equipment/devices & In-vitro diagnostics

I.P.E.

MvPI participation in Indian Pharma Expo

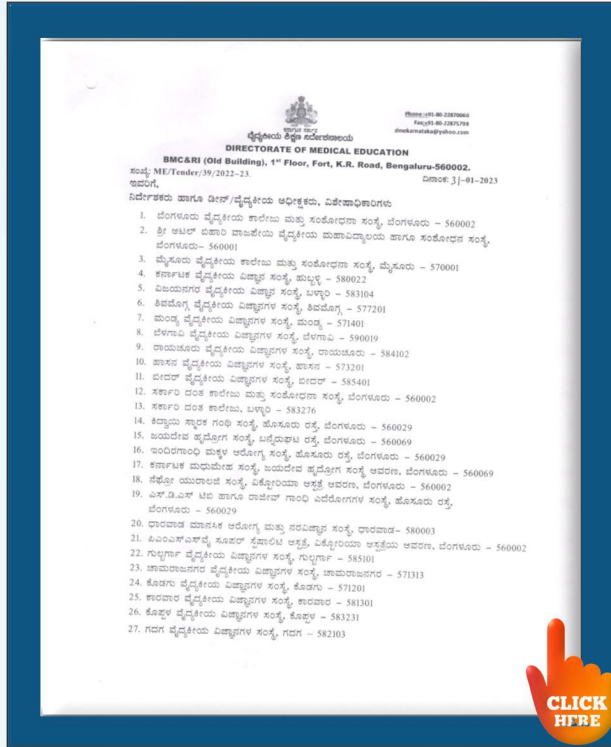


72nd Indian Pharmaceutical Congress organized by Indian Pharmaceutical Congress Association on "Access to Quality & Affordable Medical Products" from January 20-23, 2023 at Nagpur. Dr. V Kalaiselvan, Senior Principal Scientific Officer presented a session in the said conference. IPC Team had step up a stall in Indian Pharma Expo to showcase the resource material of IPC. Mr. Rohit Sharma, Junior Materiovigilance Associate also participated in the conference and enhanced the knowledge of attendees of what, whom and where to report medical device associated adverse events.



G.N.

Government Notification on MvPI

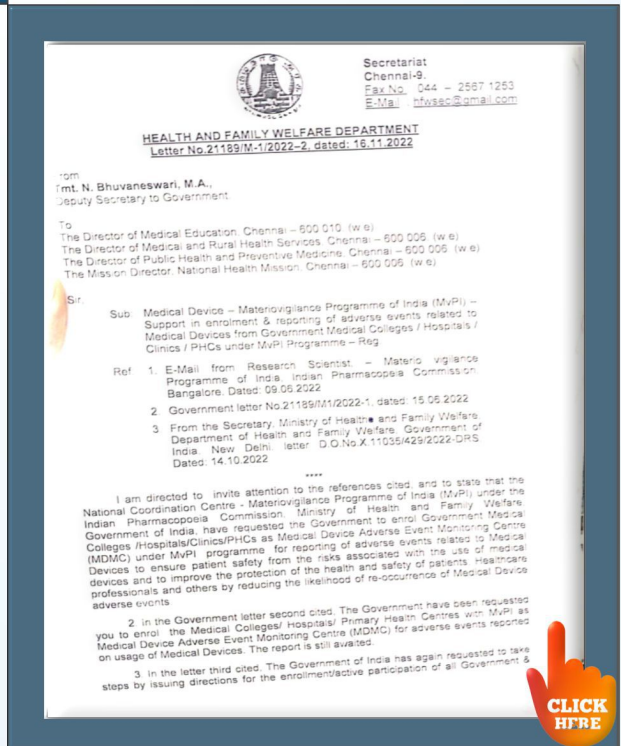


Government of Karnataka

Government of Karnataka has issued an order to medical superintendents and head of the institutions/hospitals to participate under MvPI and report medical device adverse events, if any to MvPI, IPC.

Government of Tamil Nadu

Government of Tamil Nadu has issued an order to Director of Medical Education, Director of Medical and Rural Services, Director of Public Health and Preventive Medicine and Mission Director, National Health Mission, Chennai to participate under MvPI and report medical device adverse events, if any to MvPI, IPC.



MEDICAL DEVICE UPDATE

CDSCO has updated the list of medical devices testing laboratory (MDTL) for carry out test or evaluation of medical device on behalf of manufacturer registered with CDSCO under MDR 2017.

No. 29/Misc/03/2019-DC (211)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Devices and Diagnostics Division) 07 MAR 2023

Subject: List of the certified Medical Device Testing Laboratory (MDTL) under MDR, 2017- regarding

This office had registered a Medical Device Testing Laboratory (MDTL) to carry out test or evaluation of a medical device on behalf of the manufacturer (Form MD-40 of Medical Devices Rules, 2017).

The updated list of medical devices testing laboratories registered with CDSCO under the provisions of Medical Devices Rules, 2017 to carry out test or evaluation of a medical device on behalf of manufacturer is given below:

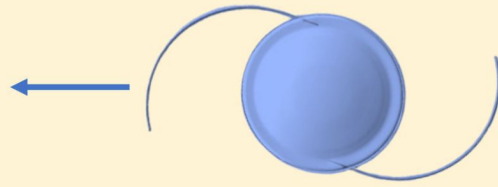
Sl. No.	NAME & ADDRESS OF MEDICAL DEVICE TESTING LABORATORY	REGISTRATION NO.	SCOPE OF TESTING
1	M/s SIPRA LABS LIMITED Address: 7-2-1813/5/A, Adj. To Post Office, Industrial Estate, Sanathnagar, Telangana, Hyderabad- 500018	TL/MD/2019/000001	1. Copper -T 2. Condoms 3. Sterile Hypodermic Needles 4. Tubal Rings 5. Hypodermic Syringes 6. Blood Bags
2	M/s Star Imaging & Path Lab Pvt. Ltd. Address: 4B/4, Tilak Nagar, West Delhi, Delhi (India) - 110018	TL/MD/2019/000002	1. Bilirubin (Total and Direct) Test Reagents / Kits 2. Creatinine test reagent / kit 3. Aspartate Amino Transferase (AST / SGOT) test 4. Alanine Amino Transferase (ALT/SGPT) test 5. Uric Acid Test reagents / kits 6. Total Protein test reagents / kits 7. Activated partial thromboplastin time (APTT) test 8. PT (Prothrombin Time) Test reagents / Kits
3	M/s Alcatec Research Laboratories India	TL/MD/2019/000003	1. Sterilized Surgical Ligatures 2. Sterilized Disposable Device



Case Study on Intraocular Lens

Adverse Events

- Toxic Anterior Segment Syndrome (TASS)
- Post Operative endophthalmitis
- Severe Eye Inflammation



Regulated in Class C

Intraocular lens

Material Used- Polypropylene
Acrylic, Silicone Hydrophobic/
Hydrophilic acrylic, Hydrogel

NCC-MvPI, IPC

Product
suspected to
Quality
related Issue

Suggested to
test the sample
in CDSCO
notified medical
device
laboratory.

Recommend to
CDSCO for their
information and
necessary
actions at their
end.

SAFETY ALERTS

NCC-MvPI, IPC has observed an adverse event report of Stem Breakage associated with the use of Orthopaedic Megaprosthesis (Femoral Stem) which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Orthopedic Megaprosthesis (Femoral Stem)	Stem Breakage

NCC-MvPI, IPC has observed an adverse event report of Atypical Mycobacterial Infection associated with the use of Monofilament synthetic absorbable skin support & filling thread sterile which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Monofilament synthetic absorbable skin support & filling thread sterile	Atypical Mycobacterial 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.

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.

PUBLICATION




NCC-MvPI has published an article entitled “Safety Monitoring of Orthopaedic implants under the Materiovigilance Programme of India - A current perspective” in the Journal of Orthopaedic Reports DOI: 10.1016/j.jorep.2023.100145.

Safety Monitoring of Orthopaedic implants under the Materiovigilance Programme of India – A current perspective

March 2023

DOI: 10.1016/j.jorep.2023.100145

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 Vivekanandan Kalaiselvan ·  Shubhang Arora ·  Rajeev Singh Raghuvarshi

Recommendations to Central Drugs Standard Control Organization (CDSCO)

1

NCC-MvPI sent a recommendation to CDSCO on "Counterfeit Device" associated with "Basic Male Condom" for information and necessary actions at their end.

2

NCC-MvPI sent a recommendation to CDSCO on "Toxic Anterior Segment Syndrome (TASS)" associated with "Intra-ocular Lens (IOL)" for information and necessary actions at their end.

3

NCC-MvPI sent a recommendation to CDSCO on "Counterfeit Device/Improper dose delivery/no medicament released/dose meter error/Ineffective drug" associated with "Meter-dose Inhaler (MDI)" for information and necessary actions at their end.



www.ipc.gov.in



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ADR Mobile-app



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1800 180 3024

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Ministry of Health & Family Welfare
Government of India

Sector-23, Raj Nagar, Ghaziabad - 201002

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For any other Information/Suggestion Query Contact:

Materiovigilance Programme of India

Email : lab.ipc@gov.in, mvpi.ipcindia@gmail.com

Website : www.ipc.gov.in

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