



सत्यमेव जयते

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Materiovigilance Programme of India

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Indian Pharmacopoeia Commission

Ministry of Health and Family Welfare (MoHFW) Government of India

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New MDMCs

Medical Device Adverse Event Monitoring Centres (MDMCs)

SGT University
Budhera, Gurugram,
Badli Road,
Haryana-122505

Type of Hospital : Non-Government
Coordinator : Ms. Poonam Salwan
Deputy Coordinator : Ms. Suman Devi
E-mail ID : salwanpoonam@yahoo.co.in

01

**Advanta Super
Speciality Hospital**
Near Bank of Baroda,
Silani Gate, Jhajjar,
Haryana-124103

Type of Hospital : Non-Government
Coordinator : Mr. Deepak
Deputy Coordinator : Mr. Chandroop
E-mail ID : ghangasmal@gmail.com

02

Navin Hospital
Nh01 Sector-3, Vaishali,
Near Mahagun Mall,
Ghaziabad,
Uttar Pradesh- 201010

Type of Hospital : Non-Government
Coordinator : Mr. Vijender
Deputy Coordinator : Mr. Ashwani Chaudhary
E-mail ID : biomedical@navinhospital.com

03

Bhardwaj Hospital
NH1 Sector-29, Noida,
Uttar Pradesh-201301

Type of Hospital : Non-Government
Coordinator : Moh. Shahnawaz
Deputy Coordinator : Mr. Raghunath Singh
E-mail ID : shahnawaz.bme@gmail.com

04

Regency Hospital A2, Sarvodaya Nagar, Kanpur, Uttar Pradesh -208005	Type of Hospital : Non-Government Coordinator : Mr. Shashank Gupta Deputy Coordinator : Mr. Madkunwar Singh E-mail ID : shashankregency@gmail.com	05
Rani Durgavati Medical College Naraini Road, Banda, Uttar Pradesh-210001	Type of Hospital : Government Coordinator : Dr. Veerendra Singh Yadav Deputy Coordinator : Mr. Sunil Kumar E-mail ID : veeru.sy11@gmail.com	06
Heritage Hospitals Limited Near Madhav Market, Lanka, Varanasi, Uttar Pradesh -221005	Type of Hospital : Non-Government Coordinator : Mr. Mithilesh Rai Deputy Coordinator : Mr. Gyanendra Singh E-mail ID : biomedical@heritagehospitals.com	07
Vinayak Hospital NH1, Sector-27, Gautam Budh Nagar, Noida, Uttar Pradesh-201301	Type of Hospital : Non-Government Coordinator : Ms. Meenakshi E-mail ID : meenakshimandal35087@gmail.com	08
Apollo Children Hospital No-15, Shafee Mohammed Road, Thousand Lights West, Chennai, Tamil Nadu-600006	Type of Hospital : Non-Government Coordinator : Ms. Sindhu Deputy Coordinator : Ms. Sumath E-mail ID : biomedicalach_cni@apollohospitals.com	09

Apollo Speciality Hospitals
Chennai Bypass Road,
Ariyamangalam,
Old Palpannai, Trichy,
Tiruchirappalli,
Tamil Nadu-620010

Type of Hospital : Non-Government
Coordinator : Mr. J. Lakshmanan
Deputy Coordinator : Mr. P. Manoj Kumar
E-mail ID : jaylakshmanan_bems@sindoorifaber.com

10

St. Thomas Hospital
Defence Colony 1st Ave,
Seven Wells, St. Thomas
Mount, Chennai,
Tamil Nadu- 600016

Type of Hospital : Non-Government
Coordinator : Mr. Uvaraj P
Deputy Coordinator : Ms. Priya C
E-mail ID : uvibme@gmail.com

11

Apollo Speciality Hospitals
Vanagaram to Ambattur
Road, Chennai,
Tamil Nadu-600096

Type of Hospital : Non-Government
Coordinator : Mr. T. Srisailan
Deputy Coordinator : Mr. V. Kannan
E-mail ID : srisai_bems@sindoorifaber.com

12

Belle Vue Clinic
Dr. U. N Brahmachari Street,
Kolkata,
West Bengal-700017

Type of Hospital : Non-Government
Coordinator : Ms. Debasmita Gangopadhyay
Deputy Coordinator : Mr. Mousam Roy
E-mail ID : biomedical@bellevueclinic.com

13

BM Birla Heart
Research Centre
National Library Avenue,
Kolkata,
West Bengal-700027

Type of Hospital : Non-Government
Coordinator : Mr. Sujit Giri
Deputy Coordinator : Mr. Sudhakar Rao
E-mail ID : sujit.giri1@ckbirlahospitals.com

14

Fortis Hospital Limited Bannerghatta Road, Opposite IIM-B, Bangalore, Karnataka-560076	Type of Hospital : Non-Government Coordinator : Mr. Arun. K.C Deputy Coordinator : Ms. Pramada Kumari Nair C.K E-mail ID : arun.kc@fortishealthcare.com	15
District Hospital Udupi, Ajjovkadu, Brahmagiri, Udupi, Karnataka-576101	Type of Hospital : Government Coordinator : Dr. Ganapati Hegde Deputy Coordinator : Dr. Divya E-mail ID : dr.ganapati.hegde@gmail.com	16
GCS Medical College Opposite DRM Office, Near-Chamunda Bridge, Naroda Road, Ahmedabad, Gujarat -380025	Type of Hospital : Non-Government Coordinator : Dr. Vipul Chaudhary Deputy Coordinator : Mr. Saad Puthawala E-mail ID : drvip79@yahoo.co.in	17
Fortis Hospital Ludhiana, Village Mundian Kalan, Chandigarh, Ludhiana Road, Punjab-141015	Type of Hospital : Non-Government Coordinator : Mr. Parminder Singh Deputy Coordinator : Mr. Gurpreet Singh E-mail ID : parminder.jassal@fortishealthcare.com	18
IVY Health and Life Sciences Private Limited Village Heir, Ajnala Road, Near Airport, Amritsar, Punjab-143001	Type of Hospital : Non-Government Coordinator : Mr. Baljeet Singh Deputy Coordinator : Dr. Manpreet Kaur E-mail ID : biomedical.asr@ivyhospital.com	19

**Jawaharlal Nehru
Medical College
Sawangi (Meghe), Wardha,
Maharashtra-442004**

Type of Hospital : Non-Government
Coordinator : Mr. Bipin Dayanand Mokal
Deputy Coordinator : Mr. Mangesh Raju Budhe
E-mail ID : bipin.mokal@dmimsu.edu.in

20

**Kalra Hospital SRCNC
Private Limited
Tulsi Das, Kalra Marg,
Kirti Nagar,
New Delhi-110015**

Type of Hospital : Non-Government
Coordinator : Ms. Bharti
Deputy Coordinator : Dr. Y B Sharma
E-mail ID : bme@kalrahospital.com

21

**Rajmata Shrimate Devendra
Kumari Singhdeo Medical
College
Kanyaparisar Rd, Gangapur,
Ambikapur, Surguja,
Chhattisgarh-497001**

Type of Hospital : Government
Coordinator : Dr. Pravin G. Dhone
Deputy Coordinator : Dr. Ravikant Tiwari
E-mail ID : pravin.dhone@yahoo.com

22

**Tirumala Multi Speciality
Hospital Private Limited
Lower Tank Bund Road,
Near R.T.C. Complex,
Vizianagaram,
Andhra Pradesh-535003**

Type of Hospital : Non-Government
Coordinator : Dr. Chejarla Mahesh
Deputy Coordinator : Mr. K. Naga Suresh
E-mail ID : medicaloperations@tirumalahospitals.com

23

**Travancore Medicity
Medical College
Kollam, Kerala-691020**

Type of Hospital : Non-Government
Coordinator : Dr. Lyla K.N
Deputy Coordinator : Dr. Jihana Shajahan
E-mail ID : lylakurup@gmail.com

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Training & Education



To foster the culture of adverse event reporting and capacity building of healthcare professionals at the centres, MvPI team conducted a training programme at Yashoda Super Speciality Hospital, Ghaziabad, a Medical Device Adverse Event Monitoring Centre (MDMC) under MvPI on March 08, 2022. Mr. Manish Soni and Mr. Rohit Sharma sensitized 40 healthcare professionals including doctors, technicians, biomedical engineers, nurses, pharmacists of Yashoda super speciality hospital on "Materiovigilance programme and reporting of medical device adverse events".

MvPI team also detailed the audience about the ongoing MvPI study based on knowledge, attitude and practice of healthcare professionals.



8th MARCH, 2022



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a training programme at Paras hospital, Faridabad, a Medical Device Adverse Event Monitoring Centre (MDMC) under MvPI on "Importance of Materiovigilance programme and medical device adverse events reporting" on March 10, 2022. Mr. Manish Soni and Ms. Nikita Mishra sensitized 30 healthcare professionals including doctors, technicians, biomedical engineers, nurses, pharmacists and dieticians of Prayag hospital on programme overview, how, when and what to report, available tools for reporting medical device adverse events in materiovigilance programme.

MvPI team also clarified the roles and responsibilities of coordinators and deputy coordinators of MDMCs under MvPI. MvPI team also detailed the audience about the ongoing MvPI study based on knowledge, attitude and practice of healthcare professionals.



10th MARCH, 2022



Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in association with the Federation of Indian Chambers of Commerce and Industry (FICCI) organized 7th edition of the International Conference on Pharmaceuticals & Medical Devices Industry i.e.- India Pharma 2022 & India medical Device 2022 from April 25-27, 2022 at Dr. Ambedkar International Conference, New Delhi. Hon'ble Dr. Mansukh Mandaviya, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India (GOI) inaugurated the conference by lighting the lamp. The other dignitaries such as Shri Bhagwanth Khuba, Minister of State for Chemicals and Fertilizers, GOI along with Dr. Vinod K Paul, Member, National Institution for Transforming India (NITI Aayog), Government of India, Ms. S. Aparna, Secretary, Department of Pharmaceuticals (DOP), Ministry of Chemicals and Fertilizers, GoI, Dr. Balram Bhargava, Director General, Indian Council of Medical Research (ICMR), Mr. Kamlesh Kumar Pant, Chairman, National Pharmaceutical Pricing Authority (NPPA) were also present during the event on April 25, 2022 at Dr Ambedkar International Centre, New Delhi. In the conference, NCC-MvPI has conducted a workshop on "Materiovigilance Programme of India" on April 25, 2022. In the workshop, opening remarks presented by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC. 1st Session on "Materiovigilance Programme of India: An Overview" deliberated by Dr. V. Kalaiselvan, Senior Principal Scientific Officer, IPC.

25th - 27th APRIL, 2022

2nd Session on "Medical Device Regulatory Framework: Indian perspective" deliberated by Dr. Ravi Kant Sharma, Deputy Drugs Controller (India), Central Drugs Standard Control Organization (CDSCO). 3rd Session on "Medical device adverse event monitoring in hospitals: Current practice & Trend analysis" deliberated by Dr. Harmeet Singh Rehan, Director and Head, Department of Pharmacology, Lady Hardinge Medical College, New Delhi. 4th Session on "Engagement of medical device industries in medical device adverse event reporting" deliberated by Mr. Animesh Thakur, Head, Quality Assurance India, Boston Scientific India Private Limited. 5th Session on "Medical device adverse event reporting tools & uses: Case Study analysis" deliberated by Dr. Shatrunjay Shukla, Scientific Assistant, IPC. IPC team also setup a stall from 25th -27th April 2022 to showcase the resource materials of IPC programmes & promote the patient safety in which approx. 70 stakeholders visited IPC stall.



National Health System Resource Centre, New Delhi, health technology division and WHO Country office organized two-days workshop on "Preparedness for Resilient Health Systems" on May 30-31, 2022 at Radisson Blu Plaza Delhi Airport, New Delhi. Dr. Shatrunajay Shukla, Scientific Assistant presented a session on "Introduction to MvPI- Patient safety and adverse event reporting" on the said workshop. Around 150 participants participated in this workshop. Audience of the workshop enhanced their knowledge on safety surveillance of materiovigilance system in India.

30th - 31st MAY, 2022



Road Map to connect Medical Device Industry in MvPI

National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) team physically visited Terumo India Private Limited, Gurgaon on May 12, 2022. MvPI team developed their basic understanding on Quality Management System (QMS) required for medical devices such as cardiac stents, vascular closure devices, heart lung machines etc. manufactured by Terumo company. MvPI team also had a discussion with Dr. Amit Garg, Director Medical & Clinical Affairs and Strategy Planning and his team on essential information to capture in Medical Device Adverse Event Reporting Form & team has also visited Terumo skilled laboratory where they provided hands on training to novel doctors.



Glimpse of visit at Terumo India Private Limited, Gurgaon

MvPI, a mandatory requisite for Hospitals under NHM, Kerala

Government of Kerala has issued an order to the hospitals/institutions under National Health Mission, Director of Health Services and Director of Medical Education, Thiruvananthapuram to enroll under Materiovigilance Programme of India.

G.O.(Rt)No.533/2022/H&FWD



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department-Permission to DME and DHS institutions for enrolling in to Materiovigilance Programme of India through National Health Mission-Granted-Orders issued.

HEALTH & FAMILY WELFARE(F)DEPARTMENT

G.O.(Rt)No.533/2022/H&FWD Dated,Thiruvananthapuram, 10-03-2022

Read 1 Letter No DCG(I)/Misc./2017(141) dated 8/12/2017 from Drugs Controller General (India)

2 Letter No.NHM/3227/E2/2018/SPMSU from State Mission Director, National Health Mission dated 31/10/2021

ORDER

The Materiovigilance Programme of India (MvPI) aims to monitor report and analysis of adverse event associated with the use of Medical Device as a step forward promoting patient safety. Materiovigilance Programme of India (MvPI) also aims to collect data on Medical Device related adverse events systematically ,and scientifically analyse them to aid in regulatory decisions and recommendations on safe use of medical devices being made using data generated from India. The programme is meant to monitor medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

2. As per letter read as 1st paper above Drugs Controller General of India requested to expedite the process of Medical devices Adverse Events reporting to Indian Pharmacopoeia Commission or Materiovigilance Programme of India designated centres of PAN India.

3. As per letter read as 2nd paper above SMD National Health Mission has proposed the followings regarding the same :

- The adverse events reporting system may be internally monitored by the Biomedical Engineering wing of National Health Mission Kerala(NHM). The

G.O.(Rt)No.533/2022/H&FWD

district biomedical engineer may be assigned as the coordinator of the institutional committee of the corresponding hospitals in the district. MvPI will provide training to the Head of Institutions and District Biomedical engineers, to avoid the misuse of information. The entire system in the state will be monitored by the Biomedical wing of NHM Kerala.

- The reported adverse event will be analyzed by a committee constituted by Indian Pharmacopoeia Commission (IPC), Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), National Health System Resource Centre (NHSRC) and Central Drugs Standards Control Organisation (CDSCO). If the committee find the issue is related to the malfunctioning of equipment, the same will be informed to the manufacturer and steps will be taken for rectification.

4. Government examined the matter in detail and are pleased to grant permission to DME and DHS institutions for enrolling in to the Materiovigilance Programme of India through the institutional arrangements of National Health Mission Kerala.

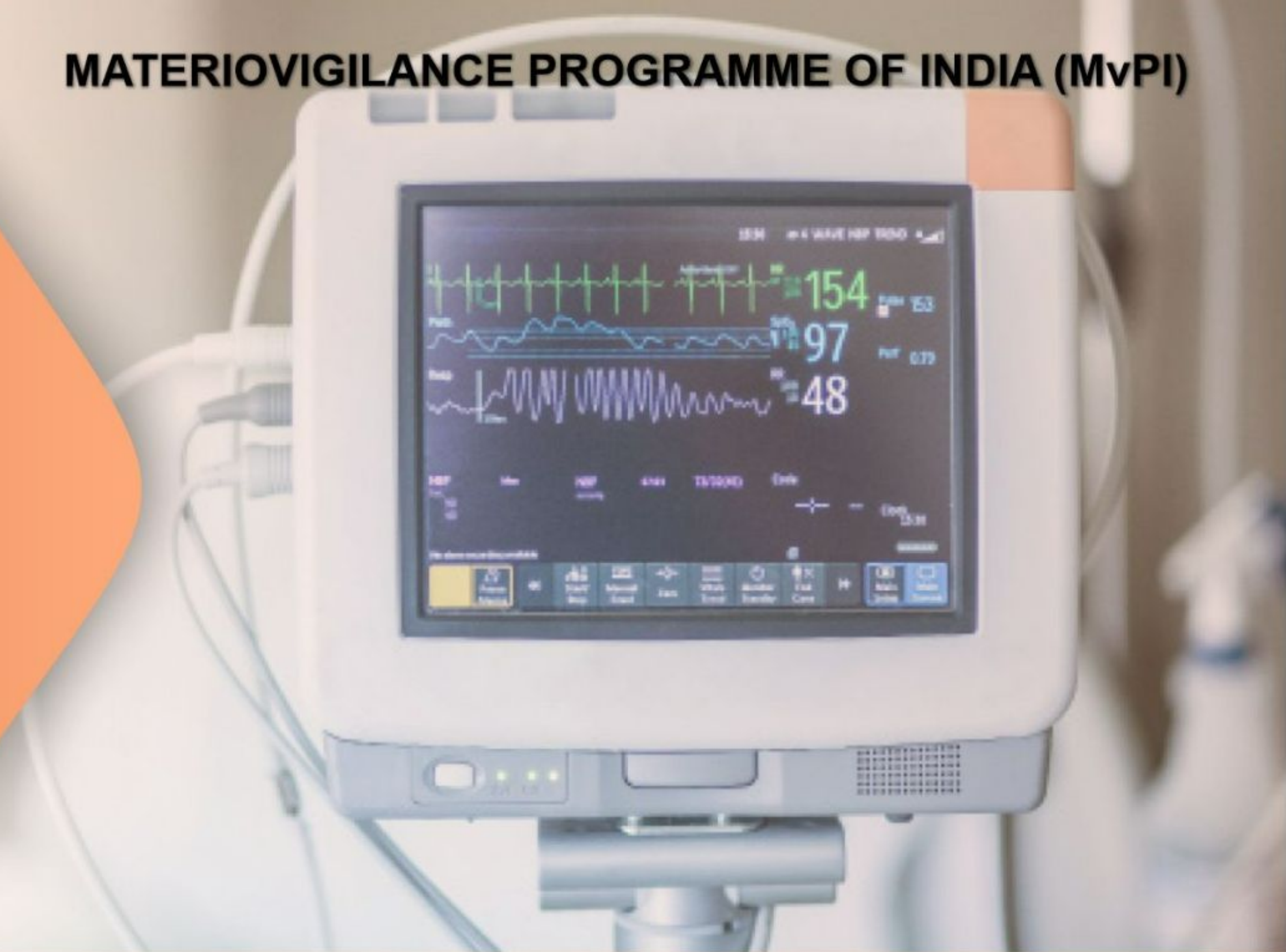
(By order of the Governor)
B SURENDRAN PILLAI
ADDITIONAL SECRETARY

State Mission Director,National Health Mission,Thiruvananthapuram
Director of Medical Education,Thiruvananthapuram
Director of Health Services,Thiruvananthapuram
Principal Accountant General(Audit/A&E)Kerala,Thiruvananthapuram
Information &Public Relations(Web & New Media)Department
Stock File/Office Copy

Forwarded /By order

Section Officer

MEDICAL DEVICE UPDATE



Central Drugs Standard Control Organization (CDSCO) has amended 43 A "Suspension & cancellation of licence" in Medical Device Rules, 2017.

**MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)**

NOTIFICATION

New Delhi, the 18th May, 2022

G.S.R. 356(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 23(E), dated the 18th January, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 19th January, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

- (1) These rules may be called the Medical Devices (Third Amendment) Rules, 2022.
(2) They shall come into force on the date of their publication in the Official Gazette.
- In the Medical Devices Rules, 2017, after rule 43, the following rule shall be inserted, namely:—
“43A. Suspension and cancellation of licence.—(1) If the manufacturer or licensee fails to comply with any of the conditions of an import license, or any provisions of the Act and these rules, the Central Licensing Authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a license issued under rules, or suspend it for such period as it may think fit either wholly or in respect of any of the part of medical device to which it relates or direct the licensee to stop import, sale or distribution of the said medical device and, thereupon, order the destruction of medical device and the stock thereof in the presence of an officer authorised by the Central Licensing Authority, if in its opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder:

Provided that a person who is aggrieved by the order passed by the Central Licensing Authority under this rule may, within thirty days of the serving of the order, file an appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity of being heard, pass such order as it thinks fit.”.

[F. No. X.11014/4/2019-DR]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 174(E), dated the 4th March, 2022.



Safety Alerts



NCC-MvPI, IPC has observed an adverse event report of required intervention due to implant deformation/ failure associated with Total Knee Replacement which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Total Knee Replacement	Implant Deformation/ failure

NCC-MvPI, IPC has observed an adverse event report of required intervention due to defective devices (Leaky) associated with vacutainers which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Vacutainers	Defective devices (Leaky)

NCC-MvPI, IPC has observed certain adverse event report of delivering improper dose/ Medicament not released/ Breathing Problem associated with Inhaler which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Inhaler	Event details Delivering improper dose/ Medicament not released/ Breathing Problem/ Issue with the pipe of inhaler/ Dose Counter Error/ not working/ Pin Broken etc.



NCC-MvPI, IPC has observed an adverse event report of required intervention due to displaced fusion device associated with Interbody System which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Interbody System	Displaced fusion device

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 reporting form after the use of these devices to NCC-MvPI, IPC via e-mail: shatrunjay.ipc@gov.in.

Message

The content of the 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.

Recommendations to Central Drugs Standard Control Organization (CDSCO)

1

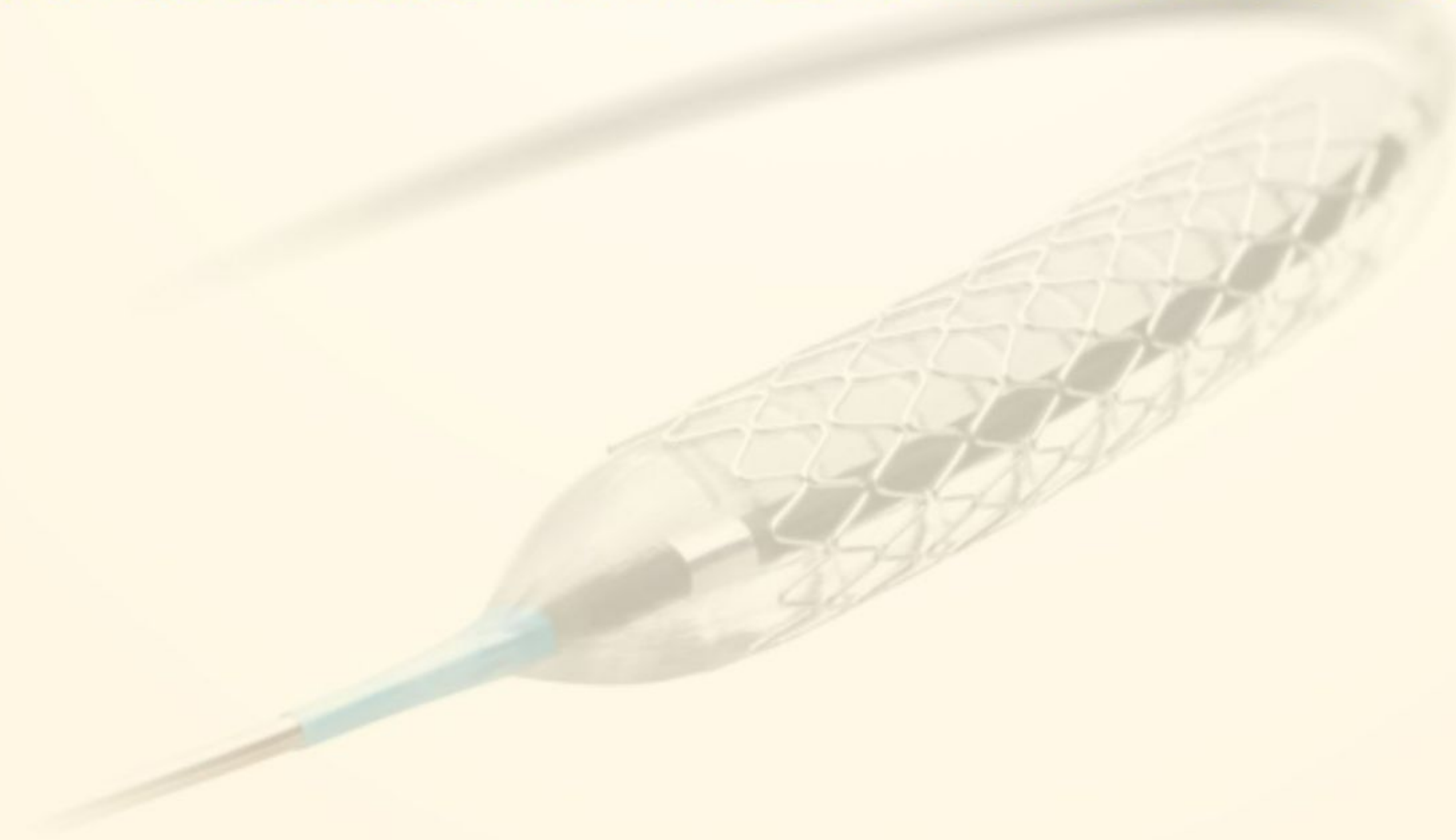
National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC sent a recommendation to CDSCO on Implant Deformation/ failure associated with Total Knee Replacement for information and necessary actions at their end.

2

National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC sent a recommendation to CDSCO on Defective devices (Leaky) associated with Vacutainers (Glucose FX) 2ml for information and necessary actions at their end.

3

National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC sent a recommendation to CDSCO on Delivering improper dose/ Medicament not released/Breathing Problem/Issue with the pipe of inhaler/Dose Counter Error/not working/ Pin Broken etc associated with Inhalers for information and necessary actions at their end.





www.ipc.gov.in



Toll Free No. : 1800 180 3024



NCC-PvPI IPC



@IPC NCC-PvPI



shatrunjay.ipc@gov.in, mvpi-ipc@gov.in



ADR Mobile-app



Helpline
1800 180 3024

Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare
Government of India

Sector-23, Raj Nagar, Ghaziabad - 201002

Tel. : 0120-2783400, 2783401, 2783392

Fax : 0120-2783311

**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