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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)

Aarupadai Veedu Medical Collage
Kirummapakkam, Puducherry

Dr. D. Y. Patil Medical College, Hospital &
Research Centre, Pune, Maharashtra

Government Medical College
Miraj, Maharashtra

Government Medical College
Palakkad, Kerala

Government Pharmacy College
East, Sikkim

Indira Gandhi Govt. Medical College & Hospital
Nagpur, Maharashtra

Indira Gandhi Institute of Medical Sciences
Patna, Bihar

Jawaharlal Medical College, AMU
Aligarh, Uttar Pradesh

New MDMCs

JSS Medical College & Hospital
Mysuru, Karnataka

Kurnool Medical College
Kurnool, Andhra Pradesh

Mahatma Gandhi Medical College &
Research Centre, Pondicherry

Mahatma Gandhi Institute of Medical Science
Wardha, Maharashtra

MGM Medical College & Hospital
Aurangabad, Maharashtra

Mamata Academy of Medical Sciences Hospital
Hyderabad, Telangana

Manipal College of Dental Sciences
Manipal, Karnataka

Shri Lal Bahadur Shastri Govt. Medical College
Mandi, Himachal Pradesh

New MDMCs

Sawai Man Singh Medical College
Jaipur, Rajasthan

Sree Narayana Institute of Medical Sciences
Ernakulam, Kerala

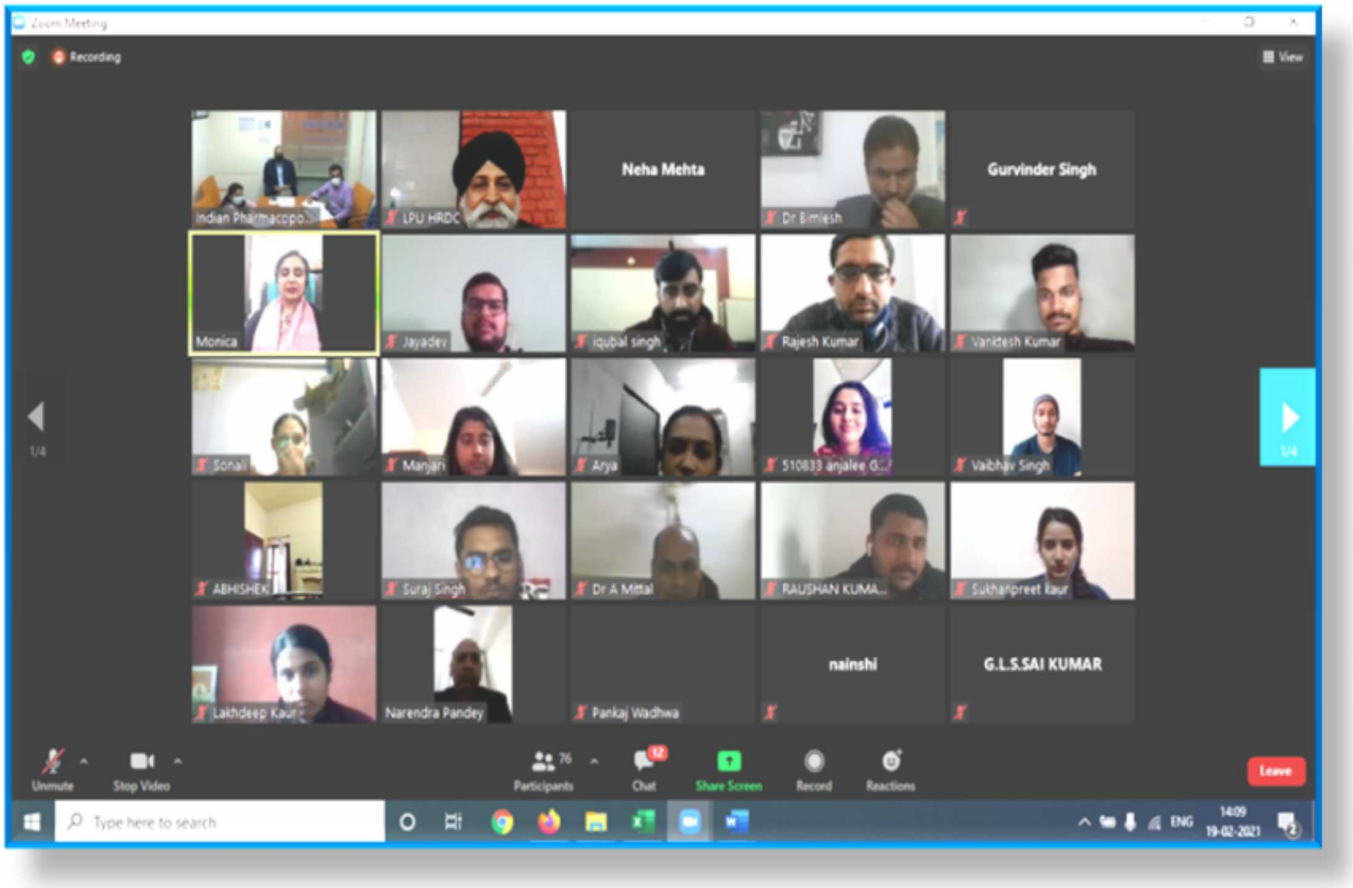
Teerthanker Mahaser Medical College &
Research Centre, Bagadpur, Uttar Pradesh

Tripura Medical College &
Dr. Bram Teaching Hospital, Agartala, Tripura

TRAINING & EDUCATION

National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in association with Lovely Professional University, Punjab organized a webinar on “Basics of Materiovigilance and hands on training on Medical Device Adverse Event (MDAE) Reporting” via digital/ virtual platform. More than 150 participants including students and faculty members of Lovely Professional University participated in this training programme. Eminent speakers i.e. Dr. Shatrunjay Shukla, Scientific Assistant, Indian Pharmacopoeia Commission, Ms. Amrutha, Scientist C, Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Dr. Santanu Tripathi, Professor from School of Tropical Medicine, Kolkata and MvPI officials have contributed in many ways to turn this event into a meaningful and interesting interactive session.

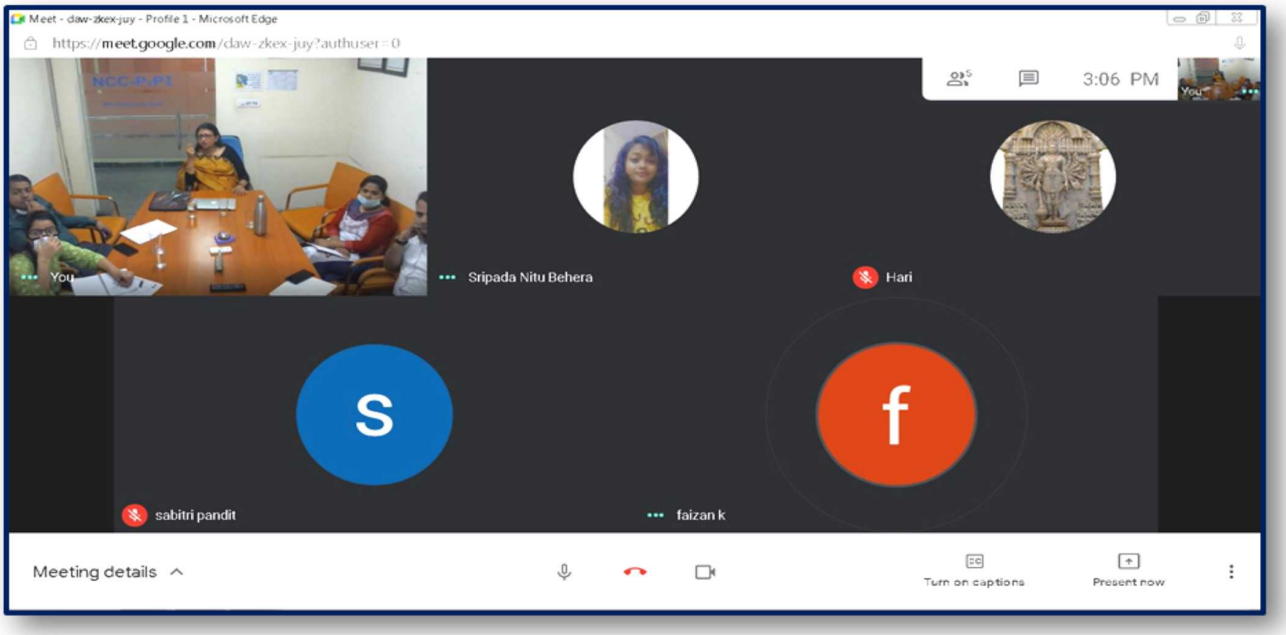
This webinar cum training programme has provided information about the importance of reporting adverse events associated with medical devices to the Materiovigilance Programme of India (MvPI) and promote the safety of medical devices.



TRAINING & EDUCATION

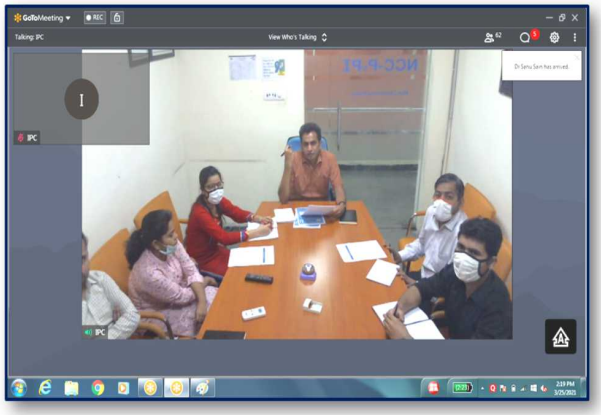
National Coordination Centre -Materiovigilance Programme of India (NCC-MvPI) in association with Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation, Chinnaavutapally, Andhra Pradesh organized a sensitization and workshop on "Materiovigilance - A Futuristic Stride" on March 09, 2021.

More than 150 students and faculty members of Dr. Pinnamaneni Siddhartha Institute of Medical Sciences and Research Foundation participated in this workshop and developed a basic understanding on Materiovigilance Programme of India. Dr. V Kalaiselvan, Principle Scientific Officer, IPC sensitized and updated the audience on the Regulatory perspective of Medical Devices in India.



National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI) organized a training programme on Case Narrative writing for reporting medical device adverse events for the associates of MvPI. Materiovigilance associates from different medical device adverse event monitoring centres (MDMC) participated in this training programme. Dr. Mita Nandy, Medical Consultant, IPC sensitized the MvPI associates on how to write case narrative and how to capture essential information in medical device adverse event reporting form.

TRAINING & EDUCATION



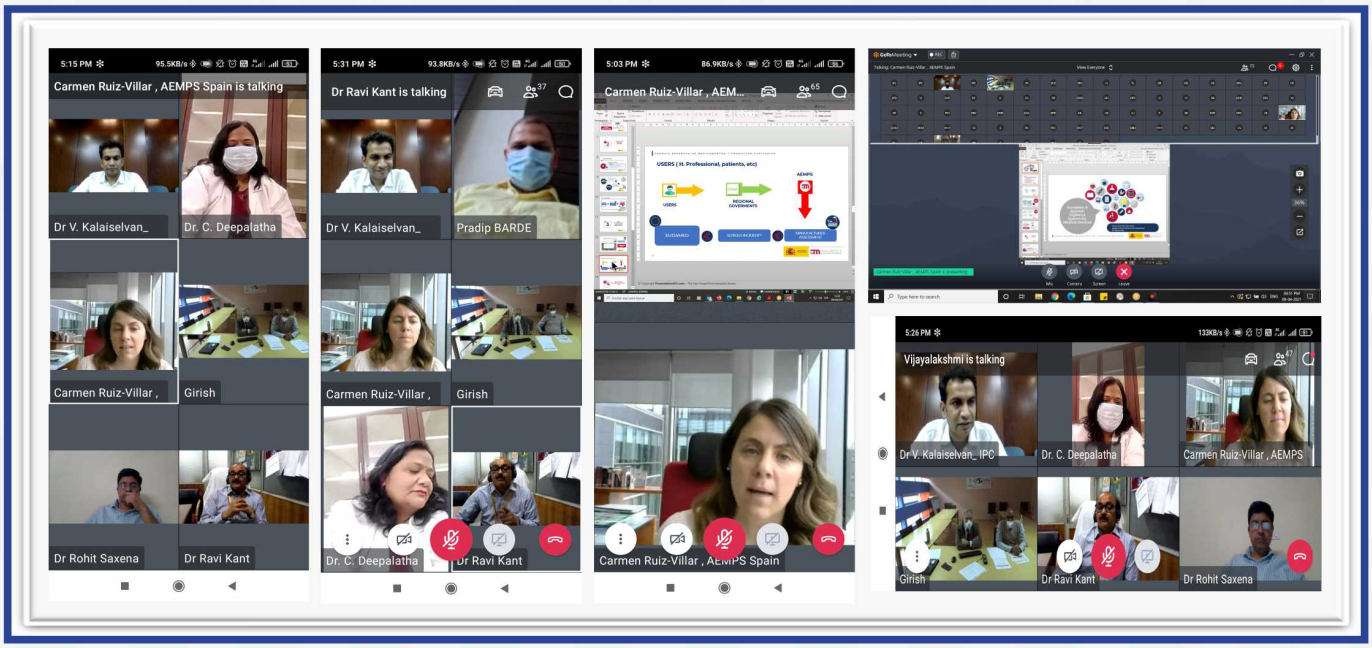
National Coordination Centre -Materiovigilance Programme of India (NCC-MvPI) in association with All India Institute of Medical Sciences (AIIMS), Patna organized a CME cum e-workshop on "Materiovigilance: Ensuring safety of Medical Devices" on March 25, 2021 via digital/virtual platform. More than 100 participants including doctors, medical officers, biomedical engineers, professor head of different departments participated in this workshop.

Specific Outcomes

- ***Capacity building of the participants on medical device adverse event reporting and case analysis.***
- ***Educated the participants on Medical Device Rules 2017, causality assessment and establishment of Medical Device Safety Monitoring System at Medical Device Adverse Event Monitoring Centre.***

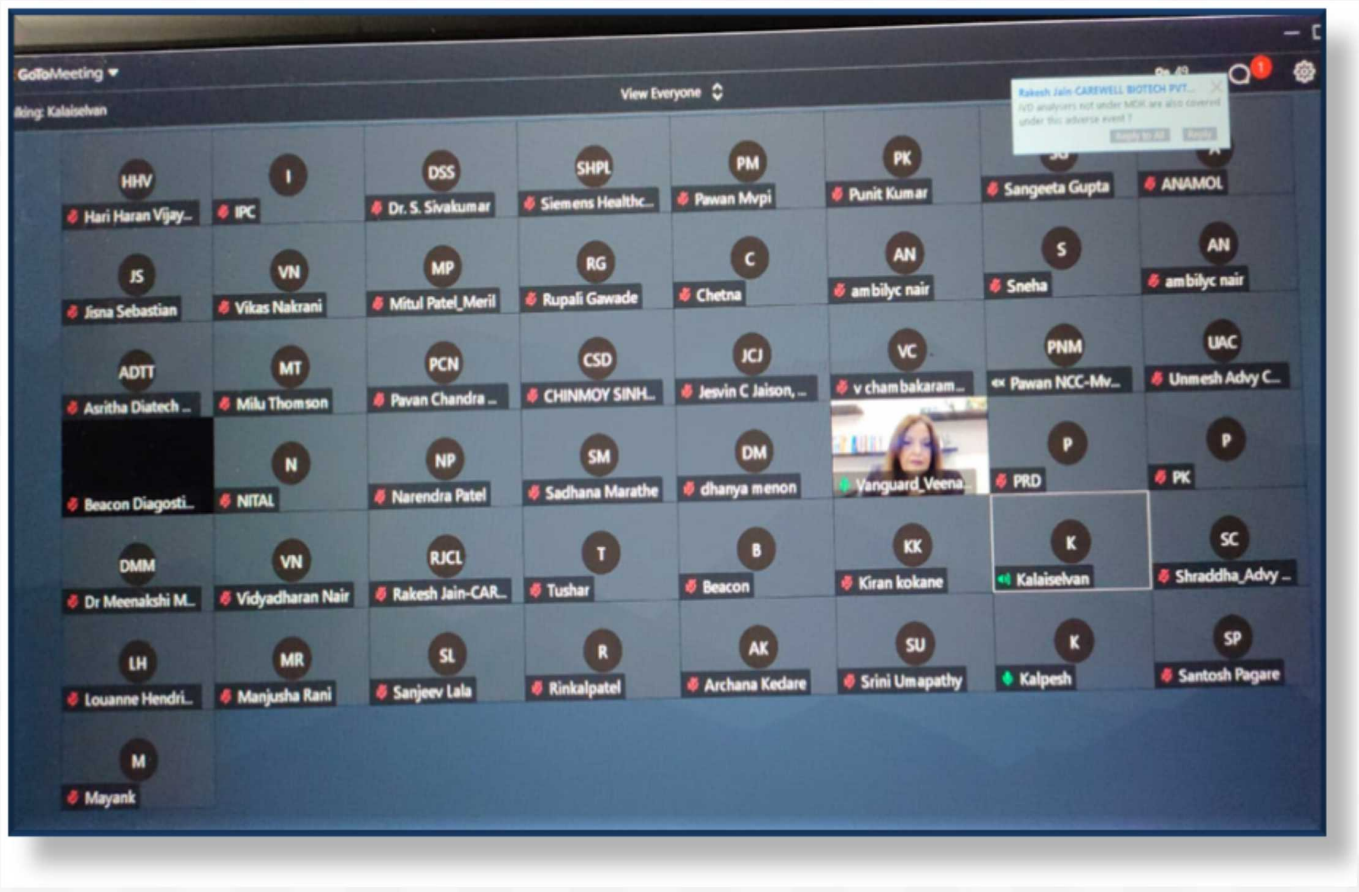
International Webinar

National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC and University of Valladolid, Institute of Applied Ophthalmobiology (IOBA), Spain jointly organized an international webinar in collaboration with Spanish Agency of Medicines and Medical Products (AEMPS), Spain on "Ensuring safety of medical devices focussed on Ocular Devices" on April 09, 2021via digital/virtual platform. The webinar was attended by around 100 participants including ophthalmologists, ocular device manufacturers, distributors, importers, healthcare professionals and researchers. In this webinar, Dr. Ravi Kant Sharma from Central Drugs Standard Control Organization (CDSCO), New Delhi spoke on Regulation of Medical Devices in India. Dr. Rohit Saxena from All India Institute of Medical Sciences (AIIMS), New Delhi spoke on Safety surveillance on Cataract and Glaucoma Devices. Dr. Bikas Medhi from Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh spoke on Regional prospective of Safety monitoring of Ocular Devices. Dr. Girish Kumar Srivastava from University of Valladolid, IOBA, Valladolid, Spain spoke on ISO Norms for Medical Devices. Dr. Jose Carlos Pastor, University of Valladolid, IOBA, Valladolid, Spain spoke on Global perspective of Perfluorocarbon Liquid (PFCL) safety and regulatory concerns and Dr. Carmen Ruiz from Spanish AEMPS, Madrid, Spain spoke on Spanish Vigilance System for Medical Devices. All the eminent speakers enlightened the audience about the safe use of ocular devices and also interacted with the audience in the question and answer session at the end of the webinar.



TRAINING & EDUCATION

National Coordination Centre -Materiovigilance Programme of India (NCC-MvPI) in association with Association of Diagnostics Manufactures of India (ADMI) organized a webinar on April 17, 2021 on "Introduction to Materiovigilance Programme of India (MvPI)& Tools of Adverse Event Reporting" via digital/virtual platform. The webinar was attended by around 50 participants including IVD manufactures. Dr. V. Kalaiselvan, Senior Principle Scientific Officer, IPC sensitized the audience about the importance of reporting associated with in-vitro diagnostics in order to promote and enhance the adverse event reporting culture among IVD manufacturers. All the available modalities of reporting were explained to the participants. The webinar was concluded by Ms. Veena Kohli, CEO, Vanguard Diagnostics Private Limited & President of ADMI and she gave her remarkable address on significance of MvPI and adverse event reporting.



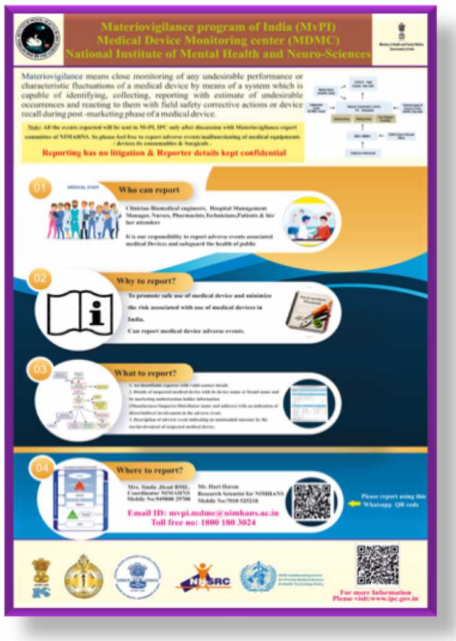
TRAINING & EDUCATION

Saheed Laxman Nayak Medical College and Hospital, Koraput Odisha, a medical device adverse event monitoring centre (MDMC) under Materiovigilance Programme of India organized a sensitization programme on “Awareness on Materiovigilance Programmes of India (MvPI)” on April 07, 2021 via digital/virtual platform. Around 50 participants participated in this programme including head of the departments and healthcare professionals. Dr. Trupti Swain, MDMC coordinator sensitized the audience about the significance of Materiovigilance Programme.

TRAINING & EDUCATION

Association of Regulatory Affairs professionals (ARAP) in collaboration with Indian Pharmaceutical Association-Delhi State Branch, organized a summit entitled “2nd Indian Regulatory & Quality Summit (IRQS) 2021” on March 23, 2021 at hotel Lalit, New Delhi. In this summit Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC addressed the gathering about IPC mandates. Dr. V Kalaiselvan, Senior Principal Scientific Officer, IPC enlightened the participants on “Recent advancement in MvPI”. MvPI officials setup a stall and created awareness on resource materials for information, education and communication about MvPI.

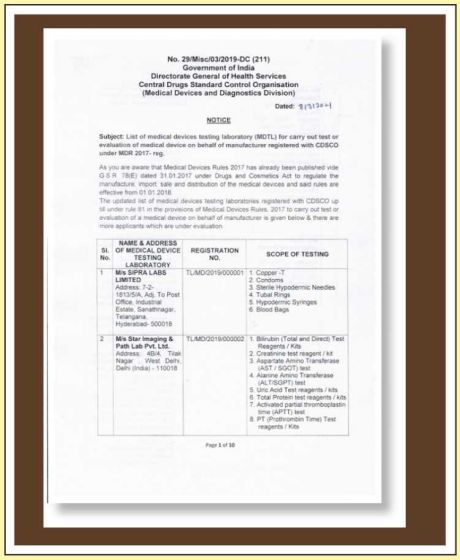
TRAINING & EDUCATION



Launching of MvPI Poster at National Institute of Medical Sciences and Neuro-Sciences (NIMHANS)

National Institute of Medical Sciences and Neuro- Sciences (NIMHANS), Bengaluru a medical device adverse event monitoring centre (MDMC) under MvPI launched MvPI poster to report adverse events associated with medical devices. On April 01, 2021, Dr. G. Guru Raj, Director NIMHANS launched poster in Head of Department meeting at NIMHANS.

MEDICAL DEVICE UPDATES



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)

Dated: 9/3/21

NOTICE

Subject: 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- reg.

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 Cosmetics Act to regulate the manufacture, import, sale and distribution of the medical devices and said rules are effective from 01.01.2018.

The updated list of medical devices testing laboratories registered with CDSCO up till under rule 81 in the provisions of Medical Devices Rules, 2017 to carry out test or evaluation of a medical device on behalf of manufacturer is given below & there are more applicants which are under evaluation.

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	TLMD/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	TLMD/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

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ITL Labs (P) Ltd., Delhi

Received approval from CDSCO under rule 81 in the provisions of Medical Device Rules, 2017, as medical device testing laboratory to conduct tests and evaluation of medical devices on behalf of manufacturer

Central Drugs Standard Control Organization (CDSCO)

Notice for SAE reporting (Serious Adverse Event) on Sugam Porter Version 1.0

- *Online submission of SAE during clinical trial of drugs & medical devices on SUGAM porter.*
- *No new offline reports will be accepted w.e.f. March 14, 2021*
- *Follow-up of already submitted reports may be submitted offline.*

F.No. CT/SAE-MISC-001/2014
Office of Drugs Controller General (India)
SAE Division

Subject: System of Pre-screening for submission of reports of SAEs to CDSCO

The Drugs & Cosmetics Rules have been amended vide GSR no 53 (E) dated 30-01-2013 inserting a Rule 122DAB, and a new Appendix-XII in Schedule "Y" along with other amendments. The amendments specifies the detail procedures for analysis of Serious Adverse Events (SAEs) including deaths occurring during clinical trial to arrive at the cause of death / injury to the subject, as the case may be, and to determine the quantum of compensation, if any to be paid by the sponsor or his representative whosoever have obtained permission from CDSCO in a time bound manner.

As per the provisions, each SAE including death is required to be examined and decision regarding causality of death and quantum of compensation, if any, is required to be taken by CDSCO in a time bound manner as per the procedure specified in Appendix XII of Schedule Y.

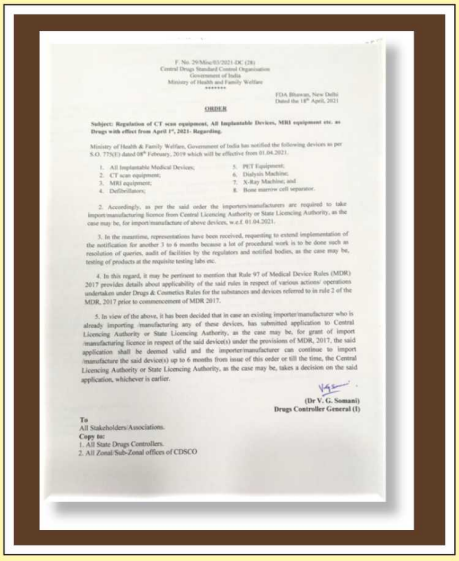
As per Appendix XII the Investigator shall report all serious and unexpected adverse events to the CDSCO, the Sponsor or his representative whosoever had obtained permission from the CDSCO for conduct of the clinical trial and the Ethics Committee, within twenty four hours of their occurrence.

The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for Conducting the Clinical Trial and the Investigator shall forward their reports on Serious Adverse Event, after due analysis to the Licensing Authority as Defined under rule 2(1h), within ten calendar days of occurrence of the Serious Adverse Event.

The Ethics Committee shall forward its report on the Serious Adverse Event, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority within twenty one calendar days of occurrence of the serious adverse event.

In case of serious adverse events of death, the reports shall be examined by an independent Expert Committee constituted by DCGI) to determine if the cause of death is due to following reasons, which are considered as clinical trial related death and gives its recommendation to CDSCO. In case of clinical trial related death the committee shall also recommend the quantum of compensation to be paid by the sponsor or his representative, to CDSCO.

a) adverse effect of investigational product(s);
b) violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator;



F. No. 29/Misc/03/2021-DC (28)
Central Drugs Standard Control Organization
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the 18th April, 2021

ORDER

Subject: Regulation of CT scan equipment, All Implantable Devices, MRI equipment etc. as Drugs with effect from April 1st, 2021- Regarding.

Ministry of Health & Family Welfare, Government of India has notified the following devices as per S.O. 775(E) dated 18th February, 2019 which will be effective from 01.04.2021.

1. All Implantable Medical Devices;
2. CT scan equipment;
3. MRI equipment;
4. Defibrillators;
5. PET Equipment;
6. Dialysis Machine;
7. X-Ray Machine; and
8. Bone marrow cell separator.

2. Accordingly, as per the said order the importers/manufacturers are required to take import/manufacturing license from Central Licencing Authority or State Licencing Authority, as the case may be, for import/manufacture of above devices, w.e.f. 01.04.2021.

3. In the meantime, representations have been received, requesting to extend implementation of the notification for another 3 to 6 months because a lot of procedural work is to be done such as resolution of queries, audit of facilities by the regulators and notified bodies, as the case may be, testing of products at the requisite testing labs etc.

4. In this regard, it may be pertinent to mention that Rule 97 of Medical Device Rules (MDR) 2017 provides details about applicability of the said rules in respect of various actions/ operations undertaken under Drugs & Cosmetics Rules for the substances and devices referred to in rule 2 of the MDR, 2017 prior to commencement of MDR 2017.

5. In view of the above, it has been decided that in case an existing importer/manufacturer who is already importing /manufacturing any of these devices, has submitted application to Central Licencing Authority or State Licencing Authority, as the case may be, for grant of import /manufacturing licence in respect of the said device(s) under the provisions of MDR, 2017, the said application shall be deemed valid and the importer/manufacturer can continue to import /manufacture the said device(s) up to 6 months from issue of this order or till the time, the Central Licencing Authority or State Licencing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

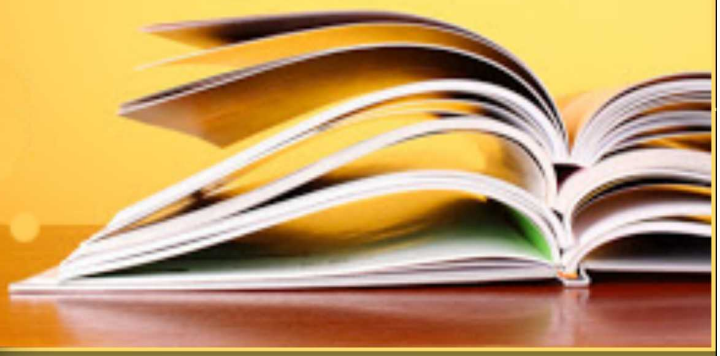
(Dr V. G. Somani)
Drugs Controller General (I)

To
All Stakeholders/Associations.
Copy to:
1. All State Drugs Controllers.
2. All Zonal/Sub-Zonal offices of CDSCO

Central Drugs Standard Control Organization (CDSCO)

Regulation of CT Scan Equipment, All Implantable Devices, MRI equipments etc. as drugs w.e.f. April 01, 2021. The said application shall me deemed valid and the importer/manufacturer can continue to import /manufacture the said devices up to 6 months from issue of this order.

PUBLICATION



NCC-MvPI, IPC published a chapter in the Open Access book, "New Insights into the Future of Pharmacoepidemiology and Drug Safety" edited by Prof. Maria Teresa Herdeiro.

IntechOpen

NOTIFICATION OF CHAPTER ACCEPTANCE

March 16, 2021, London

Dear Dr. Kalaiselvan,

It is my pleasure to inform you that the manuscript titled "Basics and essentials of Medical devices safety surveillance" has been accepted for publication.

Your chapter will appear in the Open Access book, "New Insights into the Future of Pharmacoepidemiology and Drug Safety" edited by Prof. Maria Teresa Herdeiro

Congratulations on your achievement! I would like to thank you for your important contribution to the scientific community, and for ensuring your research is freely available to readers all over the world.

We wish you every success with your publication.

Sincerely,

IntechOpen

Basics and essentials of Medical devices safety surveillance

SAFETY ALERTS

NCC- MvPI, IPC has observed certain number of reports of Cranial perforator manufactured by "Stryker Corporation" indicating device breakage during its use. The device is suspected to cause serious adverse outcomes to the patient.

S. No.	Suspected Device Details		Event Details
	Device Name	Manufacturer	
1	Cranial Perforator	Stryker Corporation	Drill bit breakage during use leading to serious patient outcome.

NCC- MvPI, IPC has observed certain number of reports of orthopedic drill manufactured by "Manman manufacturing company private limited, Maharashtra" indicating device breakage during its use. The device is suspected to cause serious adverse outcomes to the patient.

S. No.	Suspected Device Details		Event Details
	Device Name	Manufacturer	
1	Orthopedic drill	Manman Manufacturing Company Private Limited, Maharashtra	Drill bit breakage during use leading to serious patient outcome.

SAFETY ALERTS

Perfluorocarbon Liquid/Per Fluoro Octane (e.g. Bio octane, Ala ocata), heavy silicone oils and intraocular membranes staining dye etc. are suspected to cause serious adverseoutcomes to the patient discussed in the following table: -

S. No.	Suspected Device Details		Suspected adverse event following the
	Device Name	Use	
1	Perfluorocarbon Liquid	Used in vitreoretinal surgery as they have the ability to displace aqueous humor from the retinal surface, maintaining the adhesion between retina and retinal pigment epithelium. The major applications are as follows: • Post-operative tamponade in vitreoretinal surgery • Relocating and fixing the detached retina • Displacing the sub-retinal and sub-choroidal to fluid anteriorly • Revealing proliferative vitreous retinopathy (PVR) for further maneuvers • Protecting the macula from exposure to chemicals with potential toxicity • Assisting the removal of foreign body. • Retinal detachment with severe proliferative vitreoretinopathy • Giant tear, diabetic retinopathy (DR) • Retinopathy of prematurity (ROP) • Posterior dislocated crystalline and intraocular lenses	• Acute blindness • Moderate intraocular inflammatory reactions • Retinal necrosis • Retinal vascular occlusion • Optic nerve atrophy • Ratinal atrophy • Subretinal fibrosis • Proliferative vitreoretinopathy • Pthysis
2	Heavy Silicone Oils		
3	Intraocular membrane staining dye	Used to stain living tissues or cells for identifying ocular tissues and visualizing intraocular tissues during vitreoretinal surgery	

Note:- 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

www.ipc.gov.in

Toll Free No. : 1800 180 3024

NCC-PvPI IPC

@IPC NCC-PvPI

mvpi.ipcindia@gmail.com

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 lives