सत्यमेव जयते

IPC

e-Newsletter

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Materiovigilance Programme of India

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Contents

Secretary-cum-Scientific Director's Message

Dear Stakeholders,

It gives me immense pleasure to present the 1st edition of MvPI e-newsletter for stakeholders. We desire to publish the e-newsletter every month from now onwards and keep you updated on the news and developments related to Materiovigilance Programme of India and its functioning. In this edition we would like to enlighten you on the notable events organized at different regions of the country to create awareness about the materiovigilance among the stakeholders.

The launch of the reporting tools is the significant step that has enabled to ensure and promote the safety of medical devices efficiently. The e-newsletter shall also include the safety alerts and recalls issued by the regulators to prevent risk associated with the use of such devices. Fourteen Medical Device Adverse event monitoring centres (MDMCs) are recognized till now throughout the country and expected to increase in the near future.

The IP Commission expresses its sincere thanks and gratitude to the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) for its continued guidance, support and encouragement for bringing out the e-newsletter.

DR. G.N. SINGH
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India

About MvPI

Materiovigilance Programme of India was launched by DCG (I) on 6th July, 2015 at Indian Pharmacopoeia Commission, Ghaziabad. For Materiovigilance Programme of India (MvPI), Indian Pharmacopoeia Commission functions as National Coordination Centre (NCC). Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram shall act as National Collaborating Centre, National Health System Resource Centre (NHSRC), New Delhi, shall act as Technical support partner and Central Drugs Standards Control Organization (CDSCO), New Delhi, shall support MvPI with experience of functioning as National regulator.

Materiovigilance Programme of India (MvPI) 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 communicate the findings to all key stakeholders.

New MDMCs

Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, Tamilnadu

Focal Person - Dr. V Sarweswaran
sarvesh_59@yahoo.co.in

Royal Care Super Speciality Hospital, Coimbatore, Tamilnadu

Focal Person - Mr. D. Gandhiraj
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Mysore Medical College & Research Institute, Mysuru, Karnataka

Focal Person - Dr. Basavanna P.L
drbasavannapl@gmail.com

School of Tropical Medicine, Kolkata, West Bengal

Focal Person - Prof.(Dr.) Santanu Tripathi
tripathi.santanu@gmail.com

Lady Harding Medical College & SMT. S.K. Hospital, New Delhi

Focal Person - Dr. H.S. Rehan
harmeetrehan@hotmail.com

Training & Education

Training programme on "Role of Biomedical Engineers in Assessment of Medical Devices Adverse Events"

One day training programme on role of biomedical engineers in assessment of medical devices adverse events was organized at regional office of Indian Pharmacopoeia Commission, Hyderabad on January 30, 2019. The programme aims to accelerate the role of biomedical engineers in MvPI by engaging them in accessing the adverse events associated with the use of medical devices.

More than twenty five professionals from different healthcare facility participated in this training programme.

Training Programme on "Management and Ensuring Safety of Medical Devices"

Two day training programme on management and ensuring safety of medical devices was organized at Shastri Bhavan, Chennai on May 2-3, 2019 to sensitize healthcare professionals, manufacturers, importers and distributors of medical devices for better understanding of risk management and safety of medical devices. During the programme audience was also sensitized on newly developed MvPI reporting tools.

More than Seventy five professionals from different Medical Device Industry and Government Organization participated in this training programme.

MvPI Partners Meeting

Indian Pharmacopoeia Commission (IPC) - National Coordinating Centre (NCC) for Materiovigilance Programme of India (MvPI) has started Monthly Partners Meeting from January 2019 onwards for better communication among programme partners as well as quick disposition of technical issues related to medical device adverse events. First MvPI partners meeting held at IPC, Ghaziabad on 9th January, 2019.

Safety communication has been issued by CDSCO to check for Premature Battery Depletion in Certain Medtronic Pacemakers (MODEL: Azure, Astra, Percepta, Serena, Solara) on 20-05-2019.

Recommendations for Patients & Caregivers

01 Check that home monitoring transmissions are successful and occurring at the prescribed times so healthcare providers receive notifications of battery level drops to help inform care decisions.

02 Always keep the remote monitor plugged in. Monitor your MyCareLink Heart App on your smart phone to check for changes to your battery level.

03 Seek immediate medical care if you feel dizzy, lightheaded, chest pain, severe shortness of breath or if you are caring for someone who has lost consciousness. These may be signs your device's battery has had a sudden drop.

04 Talk to your healthcare provider about whether your device is affected, how best to manage your medical condition and what actions to take with your device.

05 Contact Medtronic Technical Services Monday through Friday at 1-800-505-4636, if you have any questions.

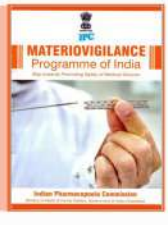
Launch of Reporting Tools to ensure patient safety

***NCC-MvPI** launched MvPI Reporting Tools and reference documents to ensure effective implementation of MvPI as well as to promote safety of Medical Devices on February 8, 2019 at IPC. Reporting tools and documents are as follows:*

Medical Device Adverse Event (MDAE) Reporting Form (Version 1.1)

A Field Safety Corrective Action (FSCA) Form

A Handbook for MvPI



Registered Medical Devices Information Sharing Portal (www.mvpi.co.in)

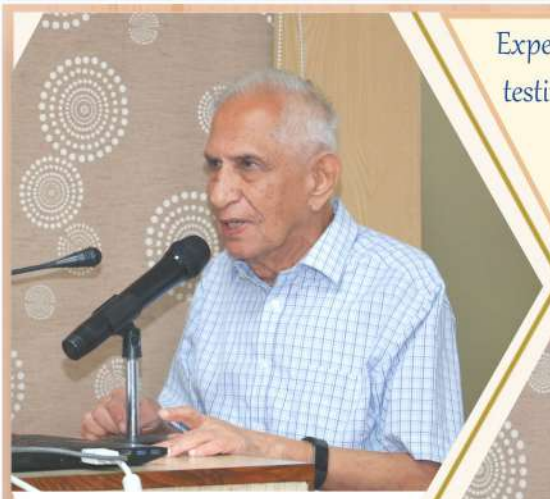
A Reference Manual for Medical Devices

Medical Devices Rules, 2017 updates

Classification of newly notified Medical Devices is provided on the website of CDSCO

S. No.	Notified Category	Intended Use	Risk Class
1	**CT scan Equipment**	Use of x-ray source and digitally scanned computer technology to create cross-sectional images of the body.	**Class C**
2	**MRI Equipment**	It is a medical imaging procedure using radio waves, magnetic fields, and magnetic field gradients to generate images of organs in the body	**Class C**
3	**Defibrillators**	It is a device that automatically analyzes the rhythm of heart of cardiac arrest patients and delivers an electrical shock to the heart for restoring the normal rhythm of heart.	**Class C**
4	**Dialysis Machine**	It is used for acute or chronic kidney failure that filters blood to remove excess water and waste products.	**Class C**
5	**PET Equipment**	Intended to detect the gamma radiation and positron emitting radionuclides in the body and produce cross-sectional images which reflect the distribution in the body or individual organs	**Class C**
6	**X-Ray Machine**	Use of X-rays to diagnose or treat patients by imaging the internal structure of the body to assess the abnormalities in the body	**Class C**
7	**Bone marrow cell sepa ·ator**	It is a general lab equipment to be used to isolate target cells and cells concentrate from bone and blood.	**Class B**
8	**Nebulizer**	It is device used to administer medications in the form of mist to inhale for respiratory disorders	**Class C**
9	**Blood Pressure Monitoring Devices**	It is device used to measure the diastolic and systolic blood pressures	**Class B**
10	**Digital Thermometer**	It is device used to record the body temperature	**Class B**
11	**·Glucometer**	It is a device used to measure the concentration of glucose in blood.	**Class C**

Experts who emphasized on quality, safety, testing and regulation on medical devices during the Formal Launch of MvPI Reporting Tools
February 08, 2019



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