सत्यमेव जयते

IPC

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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

CONTENT

Meet our New Team Members

AIIMS, PATNA

ST. JAMES HOSPITAL, CHALAKUDY

FRONTIER LIFELINE HOSPITAL, CHENNAI

TRAINING & EDUCATION

MvPI official sensitized the stakeholders on Materiovigilance in 10th Regional workshop on Pharmacovigilance and establishment of Pharmacovigilance system in Pharmaceutical Indstries - A way forward at IMTECH, CSIR , Chandigarh on July 12, 2019. Around 35 professionals participated in this workshop

Sensitization on the concepts of medical device adverse event reporting in 12th Skill development programme on Pharmacovigilance for Medical Products at IPC Ghaziabad on July 18, 2019. Around 20 professionals participated in this workshop

A session on Materiovigilance Programme of India July 9, 2019 at M. S. Ramaiah Institute of technology & Sakra world hospital, Bangalore

Training Session on concepts and terminologies of Materiovigilance in the workshop cum training programme on Pharmacovigilance for NABH accredited hospitals at Yashoda Hospital, Kaushambi on July 26,2019

Voluntary Rapid Surviellance System

IPC is working closely with the manufacturers, creating a rapid surveillance group because they are the key person who would be able to report immediately. This would enable dissemination of information regarding field safety corrective actions helping prevent safety issues from arising in the first place.

Providing a forum for alerting IPC-MvPI to ensure an effective dissemination/coordination with the matters related to medical devices safety

Who can be the part of this team ?

CONTACT

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RECENT PUBLICATION

Reporting Medical Device Adverse Event

`A beginner's Guide'

★ **Shatrunajay Shukla**
Assistant Scientist,
Indian Pharmacopoeia Commission,
Ministry of Health and Family Welfare,
Government of India

★ **Vivekanandan Kalaiselvan**
Principal Scientific Officer,
Indian Pharmacopoeia Commission,
Ministry of Health and Family Welfare,
Government of India

★ **Gyanendra Nath Singh**
Secretary-cum-Scientific Director,
Indian Pharmacopoeia Commission,
Ministry of Health and Family Welfare,
Government of India

Reporting Medical Device Adverse Event - *`A beginner's Guide' is published in the vertical talk E-Newsletter-Asian Hospital & Healthcare Management. This article briefs about medical device adverse event reporting under Materiovigilance Programme of India.*

List of Notified Bodies

01

M/s Inertek India Pvt. Ltd.
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New Delhi - 110044 (India)
Telephone No.: 011-41595475, 9310412823
E-Mail: kamal.gupta@intertek.com

02

M/s TUV Rheinland India Pvt. Ltd.
82/A West Wing, 3rd Main Rd. 82/A West Wing, 3rd Main Rd.
Electronic City (India) - 560100
Telephone No.: 080- 46498030
E-Mail: guruprasad.hc@ind.tuv.com

03

M/s TUV Sud South Asia Pvt. Ltd.
TUV SUD House, Off Saki Vihar Road, Saki Naka Andheri (East),
Mumbai-400072 (India)
Telephone No.: 022-49035508
E-mail: info@tuv-sud.in

04

M/s Dnv GI Business Assurance India Pvt. Ltd.
Equinox Business Park, Tower 3, 6th Floor, BKC, LBS Road
Kurla West, Mumbai - 400072 (India)
Telephone No. : 022-61768909
E-mail : joher.jerwalla@dnvgl.com

05

M/s BSI Group India Pvt. Ltd.
The Mira Corporate Suites, Plot No. 1 & 2, Ishwar Nagar
Delhi - 110065 (India)
Telephone No. : 11-26929000

06

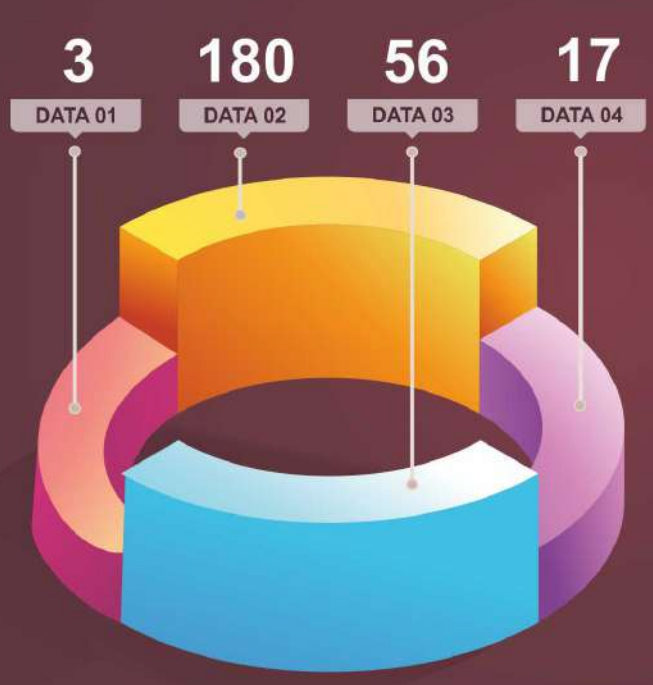
M/s BSCIC Certifications Pvt. Ltd.
Flat No. 6, Shiv Shakti, GH-15, Sec.-21C, Part - 3
Faridabad - 121001 (India)
Telephone No. : 01294175513

Baseline Study

The baseline study is a prerequisite to measure the degree and quality of the progress line of the project in order to effectively communicate for necessary actions to be taken. So the important task in the study is to collect the information and trace out the indicators which may affect the patient safety and ensure that it can be updated in the longer term.

Materiovigilance programme of India initiated the baseline study in order to trace the suspected medical devices which have been recalled or notified for field safety correction globally. In this process we circulate the information of the devices which have been recalled or notified for field safety corrective action (FSCA) from different regulators to our AMCs and MDMCs.

Analysis



DATA 01 — Baseline studies conducted

DATA 02 — Recalls / FSCA

DATA 03 — Devices Traced

DATA 04 — Organizations where deivces were traced

Medical Device Alert

Safety communication has been issued by CDSCO on July 2, 2019 regarding potential cybersecurity vulnerabilities related to MiniMed ™ Paradigm™ series insulin pumps. An unauthorized person with special technical skills and equipment could potentially connect wirelessly to a nearby insulin pump to change settings and control insulin delivery. This could lead to hypoglycemia (if additional insulin is delivered) or hyperglycemia and diabetic ketoacidosis (if not enough insulin is delivered).

Recommendations for Patients

1. Keep your insulin pump and the devices that are connected to your pump within your control at all times.
2. Do not share your pump serial number. Be attentive to pump notifications, alarms, and alerts. Immediately cancel any unintended boluses.
3. Monitor your blood glucose levels closely and act as appropriate.
4. Disconnect your CareLink™ USB device from your computer when it is not being used to download data from your pump.
5. Get medical help if you experience symptoms of severe hypoglycemia or diabetic ketoacidosis, or suspect that your insulin pump settings changed.

"Ultimately, by far the greatest benefit to patient safety will be acheived by increasing the skills and the knowledge of the many rather than penalising the very few"

- Don Berwick

Helpline : 1800 180 3024

Indian Pharmacopoeia Commission

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Government of India
Sector-23, Raj Nagar, Ghaziabad - 201002
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For any other Information/Suggestion Query Contact:

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We have started a journey of Materiovigilance, for saving lives