RECALL ALERT

DRAP ALERT NO. Nº I/07-23-29

RECALL OF IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS)
(MANUFACTURED BY M/S. MEDTRONIC, USA)

Date: 27th July, 2023

Target Audience:

- Healthcare Professionals particularly working in the critical care areas of hospitals including Physicians, Pharmacists, and Nurses.
- People implanted with affected ICDs and CRT-Ds.
- Procurement Officers at Hospitals and Healthcare Institutions.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores.

Alert Summary:

Medtronic, USA received reports for their implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) for risk of patient harm as a result of low or no energy output when high voltage therapy is needed due to inappropriate activation of the Short Circuit Protection (SCP) feature. The issue is more likely to occur for devices with a glassed feedthrough that are configured to deliver therapy in the AX>B delivered pathway. Accordingly, the manufacturing company is recalling all the defective product from the international market including Pakistan.

The detail of the affected Medical device is as under:

Brand Name	Product Description	Lot No and Codes	Manufacturer and Distributor
○ ***Cobalt XT, Cobalt, Crome ICDs and CRT-Ds*** ○ ***Claria MRI, Amplia MRI, Compia MRI, Viva, Brava CRT-Ds*** ○ ***Visia AF, Visia AF MRI, Evera, Evera MRI, Primo MRI, Mirro MRI ICDs***	Implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) are intended to monitor and regulate heart rate and rhythm	• *Medical Device Recall Database Entries [FDA} (click to open)* ***Distribution Dates**: October 13, 2017 to June 9, 2023*	Medtronic USA **Distributor in Pakistan:** M/s Medtronic Pakistan (Pvt) Ltd. Karachi.

Risk Statement:

Defective ICDs, CRT-Ds poses a risk of patient harm as a result of low or no energy output when high voltage therapy is needed. Therefore, reduced-energy shock, or no shock at all, may fail to correct a life-threatening arrhythmia, which can lead to cardiac arrest, other serious injury, or death.

Action Initiated: -

The manufacturing company has initiated a recall of the affected lots of defective devices from the market where it was distributed. All healthcare professionals working in critical care units of hospitals as well as pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying these lots of the product. The remaining stock should be quarantined and returned to the supplier/company. The regulatory field force of all federating units (DRAP and Provincial Health Departments) has also increased surveillance to monitor the recall progress to ensure effective recall.

Advice for Healthcare Professionals: -

DRAP requests to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these defective lots of the Medical Device. Patient using the affected device should immediately contact their doctors for further guidance. Furthermore, Medtronic issued an Urgent Medical Device Correction notice to customers. The communication provided the following required actions for software issue related to this recall:

- Do not prophylactically replace devices for this issue.
- Program all high voltage therapy pathways B>AX in all therapy zones to minimize the risk of this issue.
- Prioritize reprogramming patients with a history of high voltage therapy and Rx1 programmed AX>B.
- Encourage patients with AX>B programming in any high voltage therapy sequence to attend their next scheduled follow-up in-clinic for device reprogramming.
- Remotely monitor patients following normal clinical protocol.
- Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:
    - Reduced- or no-energy high voltage therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

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Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link

Advice for Consumers / General public: -

People implanted with affected ICDs and CRT-Ds or their caregivers shall immediately contact to their physician or healthcare provider if they have experienced any problems that may be related to using this Medical Device, and report the incident to National Pharmacovigilance Centre of Drug Regulatory Authority of Pakistan, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
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