PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/V/05-23-23

RECALL OF NEONATAL BREATHING CIRCUITS
(MANUFACTURED BY M/S. ARMSTRONG MEDICAL LIMITED, IRELAND)

Date: 17th May, 2023

Target Audience:

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

Alert Summary:

Armstrong Medical Limited, Ireland received reports for their Neonatal Breathing Circuits for risk of patient harm as a result of tubing (and a connector attached to the tubing) disconnecting from the elbow within Neonatal Breathing Circuits. Accordingly, the manufacturing company has issued a field safety notice and initiated recall of 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:**	**Manufacturer and Distributor**
AQUAVENT NEO neonatal CPAP limb, heated **Product Code:** 37706 **Model No. :** AMCP1409-031	Ventilator breathing circuit, single-use	**230123** as per the list in the Field Safety Notice	Armstrong Medical Limited, Northern Ireland **Distributor in Pakistan:** M/s. Elate CC (Pvt) Ltd. Karachi, Pakistan

Risk Statement:

Defective Neonatal Breathing Circuit poses a risk of patient harm as a result of tubing disconnection which could lead to delayed treatment, oxygen desaturation, lung collapse (atelectasis), failure to maintain adequate pulmonary pressure support, or failure to provide means of alveolar gas exchange, any of which could result in patient injury including cardiac arrest leading to irreparable impairment or fatality.

Action Initiated: -

The manufacturing company has initiated a recall of the affected lots of defective products 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.

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: -

Consumers should stop using this product bearing the affected batch number(s) and shall 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
محفوظ، موثر اور معیاری اشیائے علاج

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