

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
16 -08-2024

Circular No: **MSD/Q/P/2024/32**

To :

DDG/NHSL - Colombo
DDG/NH - Kandy
All Provincial Directors of Health Services,
All Regional Directors of Health Services,
All Directors of Teaching Hospitals,
All Directors of Specialized Campaigns,
Director, N.I.H.S Kalutara,
All MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry,

REPORT ON FAILING SAMPLE – Meropenem Inj. 500mg Vial

MSD ORDER LIST NO: 2022/SPC/X/C/P/00280

PA Order No: DHS/M/ICL/PM/409/2022

1. Re-above, details of the letter no NMRA/PA3/QF14/2024 dated 12.08.2024 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item : **Meropenem Inj. 500mg Vial**
Meropenem for Injection USP 500mg

SR : **00102101**

1.2) Manufacturer : Swiss Parenteral Ltd, Plot No : 402, 412-414, Kerala Industrial Estate, G.I.D.C., Nr.Bavla, Dist:Ahmedabad-382220, Gujarat, India.

1.3) Batch No. : **3323009**

1.4) Date of Manufacture : APR-2024

1.5) Date of Expiry : MAR-2025

1.6) NMQAL LR No : 39614

1.7) Analytical Report : **Failure to comply with USP specification with respect to the constituted solution test.**

1.8) SAFRES Recommendation : **To withhold the above batch from use immediately.**

2. CEO-NMRA Instruction : **Withhold above batch from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withhold the above batch from use immediately.**

3.2) To inform details of all batches available of this product to D/NMQAL, 120 Norris Canal Road, Colombo 10, to enable them to select samples for further testing and provide sample on request to NMQAL.

4. Please note: It would be your responsibility,
4.1) To follow the instructions given by Secretary of Health, under the circular No: 01/2021 dated 08.12.2021.

5. 5.1) Please bring the contents of the circular to all concerned in your Province/ Region/ Institution.

5.2) Please Note: It is the responsibility of all RDHS to ensure that the copies of this circular is circulated among all the heads of the institutions under your preview.



Dr. Dedunu Dias
Director (Acting),
Medical Supplies Division,

Dr. DEDUNU DIAS
Director - (Acting)
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw;
Colombo 10.

Cc:

1. Auditor General - f.i
2. DGHS-f.i
3. Chairman/SPC - f.i. & to inform to the supplier
4. DDG(M/S) - f.i.
5. CEO/ NMRA - f.i. & n.a.
6. Secretary/MEC - f.i
- 7. D/NMQAL** - In the event that obtaining samples from 05 different batches is not possible, to inform D/MSD to send samples from available batches.
8. Chief Internal Auditor/ MOH-f.i
9. D/ (Stock Verific.)/MOH - f.i.
10. DD/MSD - f.i. & n.a.
11. Chief Accountant/MSD-f.i & n.a
12. AD(Stores)/MSD - f.i.
- 13. Acct(S)MSD** - f.i.
14. AD (Dispatch)/MSD - f.i.
15. AD/ICT Unit - to publish in MSD web site
- 16. AD (P I)/MSD** - To ensure that SCO concerned provide the required information to NMQAL
17. All DP/DPDHS - f.i. & n.a
18. SP / MSD - f.i & n.a
19. HSCO (P) - f.i. & n.a.
- 20. SCO (S/WH 01)**- To send consignment details, storage condition and other relevant details of above product as per the request of NMRA
21. SCO (D/WH 01)-f.i & n.a
22. MSA-WH (01)/MSD - f.i. & n.a.
23. MO (Technical unit)/MOH-f.i & n.a