

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
20 -12-2024

Circular No: **MSD/Q/P/2024/52**

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 – Cefotaxime for Inj. 1g vial

MSD ORDER LIST NO: 2021/SPC/N/R/P/00030.

PA Order No: DHS/DA/308/2021.

1. Re-above, details of the letter no NMRA/PA3/QF23/2024 dated 12.12.2024 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item : **Cefotaxime for Inj. 1g vial**
Cefotaxime Sodium for injection BP 1000mg (FOTIME 1000)

SR : **00101502**

1.2) Manufacturer : **Maan Pharmaceuticals Ltd, Plot-1, G.I.D.C, Phase-II,
Modhera Road, Mehsana-384002, Gujarat, India.**

| 1.3) Batch Details | Batch | Date of Manufacture | Date of Expiry |
|--------------------|-----------------|---------------------|-------------------|
| | FA23006E | | |
| | FA23010E | 2023.01.01 | |
| | FA23013E | | 2024.12.31 |

1.4) NMQAL LR No : **39806, 39287, 39486**

1.5) Failure : **Failure to comply with BP specification with respect to the uniformity of weight, clarity and colour of solution, particulate contamination.**

1.6) SAFRESC Recommendation held on 10.12.2024 : **To withdraw the above batches based on the above mentioned NMQAL analytical reports.**

2. CEO-NMRA Instruction : **Withdraw above batches from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withdraw the above batches (as detailed in 1.1-1.3 above) 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:

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|--|--|---------------------------------------|
| 1. Auditor General - f.i | 2.DGHS-f.i | |
| 3.Chairman/SPC – f.i & n.a. | 4. DDG(M/S) - f.i. | 5.CEO/ NMRA - f.i. & n.a. |
| 6. Secretary/MEC - f.i | | |
| 7. D/NMQAL – f.i. | | |
| 8. Chief Internal Auditor/ MOH-f.i | 9.D/(Stock Verification)/MOH - f.i. | 10. DD/MSD - f.i. & n.a. |
| 11. AD (Stores)/MSD - f.i. | | |
| 12. Chief Accountant/MSD- To make arrangements to recover the relevant charges. | | |
| 13. Acct(S)MSD – To make arrangements to recover the relevant charges. | | |
| 14. AD (Dispatch)/MSD - f.i. | 15. AD/ICT Unit - to publish in MSD web site | |
| 16. AD (P)/MSD – f.i. & n.a. | | |
| 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)- f.i & n.a. | 22.MSA-WH (01)/MSD - f.i. & n.a. | 23. MO (Technical unit)/MOH-f.i & n.a |
| 21. SCO (D/WH 01)-f.i & n.a | | |
| 24. H/Destruction Unit (MSD) - f.i & n.a. | | |