

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 Injection 1g Vial

MSD ORDER LIST No: 2021/SPC/N/R/P/00030

PA No: DHS/DA/308/2021

1. Re-above, details of the Letter No: NMRA/PA3/QF23/2024 dated 06.01.2025 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item : **Cefotaxime for Injection 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 No. : **FA23014E, FA23003E, FA23002E**

1.4) Date of Manufacture : **01.01.2023**

1.5) Date of Expiry : **31.12.2024**

1.6) NMQAL LR No : **39845, 39687, 39697**

1.7) Failure : **Failure to comply with BP specifications with respect to the test for clarity and colour of solution, particulate contamination**

1.8) Recommendation of NMRA : With reference to the decision of the Safety and Risk Evaluation Subcommittee dated 02.01.2025 based on the NMQAL report LR 39845, LR 39687, LR 39697

2. CEO-NMRA Instruction : **To withdraw the above batches from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withdraw the above batches (as detailed 1.1-1.5 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.

6. Previous Circulars

Circular Number
MSD/Q/P/2024/52

Batch
FA23006E
FA23010E
FA23013E

Decision
Withdraw


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 & 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 (P3) - 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.		