

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 – Ceftriaxone for Injection 1g Vial.

MSD ORDER LIST No: 2022/SPC/X/R/P/00272

PA No: DHS/ICL/SA/251/2022

1. Re-above, details of the Letter No: NMRA/PA3/QF20/2024 dated 12.12.2024 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item	: Ceftriaxone for Injection 1g Vial Ceftriaxone for Injection USP 1g
SR	: 00101704
1.2) Manufacturer	: Swiss Parenterals Ltd, Plot No 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Nr.Bavla, Dist:Ahmedabad- 382220, Gujarat, India.
1.3) Batch No.	: 1123009
1.4) Date of Manufacture	: 01.03.2023
1.5) Date of Expiry	: 28.02.2026
1.6) NMQAL LR No	: 38809
1.7) Failure	: Failure to comply with USP specification for constituted solution test.
1.8) SAFRESC Recommendation held on 10.12.2024	: To withdraw the above batch based on the above mentioned NMQAL analytical report.

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

3. Considering above facts, you are requested the following

3.1) **To withdraw the above batch (as detailed 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:

- | | | |
|---|--|---------------------------------------|
| 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 | | |
| 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 |
| 24. H/Destruction Unit (MSD) - f.i & n.a. | | |