

Circular No: **MSD/Q/P/2026/14**

To :

DDG/NHSL – Colombo,
 DDG/NH – Kandy,
 DDG/NH – Galle,
 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 – All the Parenteral products manufactured by Maan Pharmaceutical Pvt Ltd, India

1. Re-above, details of the letters with even No. NMRA/PA3/ADR04/2025 and dated 30th June 2026 received from CEO/NMRA, are circulated herewith for your information and necessary action, please

1.1) Details of the products/ Items :

No.	SR No	Item Name
1.1.1	00303103	Ondansetron Injection 8mg in 4mL Ampoule Ondansetron Injection USP 8 mg /4 mL (Ondanman 8)
1.1.2	00102001	Imipenem 500mg and Cilastatin 500mg Injection Vial Imipenem and Cilastatin for Injection 1 g (500 mg/500 mg) - (Cimi)
1.1.3	00400401	Iron Sucrose solution for Injection/Infusion 100mg/5mL Ampoule Iron Sucrose injection USP 100 mg / 5mL (Sofer injection)
1.1.4	00101502	Cefotaxime for Injection 1g Vial Cefotaxime Sodium for Injection BP 1000mg (Fotime 1000)
1.1.5	00100905	Co-amoxiclav Injection 1000mg / 200mg Vial Co- amoxiclav for injection BP 1.2g (Manoxclav 1200)
1.1.6	00100904	Co-amoxiclav Injection 500mg / 100mg Vial Co- amoxiclav for injection BP 600mg (Manoxclav 600)
1.1.7	00300803	Haloperidol Injection 5mg in 1mL Ampoule Haloperidol Injection BP 5 mg/mL (Mancalm 5)

1.1.8	00102102	Meropenem Injection 1g Vial Meropenem for Injection USP 1 g (Manpen 1000)
1.1.9	00101001	Piperacillin 4g with Tazobactam 500mg Vial Piperacillin and Tazobactam for Injection USP 4.5 g (Bacpac 4.5)
1.1.10	00101101	Sulbactam Sodium and Cefoperazone Sodium (1:1) for Injection 1g Vial Sulbactam and Cefoperazone for Injection 1 g (Sulbactone 1)

1.2) Manufacturer : **Maan Pharmaceutical Ltd, India**

1.3) Batch Details : **All the batches of the above products / items**

1.4) Reference of NMRA : To the decisions of the **Safety and Risk Evaluation Subcommittee (SAFRESC)** held on 22nd June 2026, based on the,

- NMQUAL Reports – LR40712, LR40713, LR40714, LR40715, LR40716, LR 40717, LR 40718, LR 40719,
- Laboratory reports of Medical Research Institute – Sri Lanka and Therapeutic Goods Administration – Australia,

The aforementioned product (as detailed in 1.1.1 above) shall be withdrawn.

Additionally, taking into the consideration of above quality failure and manufacturer's refusal to undergo a GMP site inspection (communicated to the NMRA on 27.02.2025), it was decided to the above products (as detailed in 1.1.2 – 1.1.10 above) as a safety precaution.

2. CEO-NMRA Instruction : **To Withdraw the all above mentioned products from use immediately**

3. Considering above facts, you are requested the followings

3.1) To Withdraw the above mention products / items (as detailed 1.1-1.3 above) from use immediately

4. Please note: It also would be your responsibility, in addition to point 3,

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 this 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 purview.

6. Previous Circulars

Circular No	Batch	Decision
MSD/Q/P/2025/64	All the parenteral products	Withhold

Director,
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. DDG(M/S) - f.i. |
| 4. Chairman/SPC - f.i. & n. | 5.CEO/NMRA – f.i. | 6. DD/MSD - f.i. & n.a |
| 7. D/NMQAL – f.i. | | |
| 8. Chief Internal Auditor/ MOH-f.i. | 9. D/(Stock Verific.)/MOH - f.i. | |
| 10. Chief Accountant (Finance) / MSD – To make arrangements to recover the relevant charges | | |
| 11. Chief Accountant (Supplies) / MSD – To make arrangements to recover the relevant charges | | |
| 12. AD/ICT Unit – To publish in MSD web site | | |
| 13. AD(P)/MSD – f.i. & n.a. | | |
| 14. AD (M&C) – f.i. | | |
| 15. AD (Stores)/MSD - f.i. | 16. AD(Dispatch)/MSD – f.i. | |
| 17. Chairperson / MEC- f.i. | | |
| 18. All DP/DPDHS - f.i. & n.a. | 19. SP / MSD - f.i. | |
| 20. All HSCO (P) - f.i. & n.a. | | |
| 21. SCO (S / WH 01, WH 03 & WH 06) - f.i. & n.a. | | |
| 22. SCO (D / WH 01, WH 03 & WH 06) - f.i & n.a. | | |
| 23. MSA-WH (01, 03 & 06) /MSD - f.i. & n.a. | | 24. MO (Technical unit)/MOH- f.i & n.a. |
| 25. H/Destruction Unit (MSD) - f.i & n.a. | | |