

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
-01-2025

Circular No: **MSD/Q/P/2025/9**

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 Kaluthara,
All MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry

REPORT ON FAILING SAMPLE – Co-amoxiclav Injection 500mg/100mg Vial

1. Re-above, details of the letter NMRA/PA3/ADR07/2023 dated 06.01.2025 received from CEO/NMRA are given below for your information please

1.1) Name of the product/Item : **Co-amoxiclav Injection 500mg/100mg Vial**
Co.amoxiclav for injection BP 600mg (Uniclav 600mg)

SR : **00100904**

1.2) Batch No : **Product**

1.3) Manufacturer : Navesta Pharmaceutical Pvt Ltd, 107A,
Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka.

1.4) Recommendation of NMRA : With reference to the decision made by the Safety and Risk Evaluation Subcommittee on 02.01.2025 based on the NMQUAL analytical reports, the decision of product withholding has been revoked.

2. CEO-NMRA Instruction : **To revoke the decision of product withhold immediately**

3. Considering above facts, you are requested the following

- 3.1) **1 To ensure the sample testing of new batches from NMQUAL, before accepting to MSD. To revoke the product (as detailed 1.1-1.3 above) withhold decision .**
2. Do not revoke previous batch withdrawal decisions.

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

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 No	Batch	Decision
MSD/Q/P/2024/11	121123AMC1	Withhold
MSD/Q/P/2024/15	040623AMC1	Withdraw
MSD/Q/P/2024/16	121123AMC1	Withdraw
MSD/Q/P/2024/31	Batches	To withdraw the batches manufactured using API supplied by Sinochem
MSD/Q/P/2024/31(i)		
MSD/Q/P/2024/44	Product	Withhold


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. | 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.
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|---|----------------------------------|---------------------------------------|
| 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)/MSD - To ensure the sample testing of new batches from NMQUAL, before accepting to MSD | | |
| 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)- To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02 | | |
| 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 |
| 22. H/Destruction Unit (MSD) - f.i & n.a | | |