

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
-04-2025

Circular No: **MSD/Q/P/2025/16**

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, as informed by CEO/NMRA via the letter bearing the number: NMRA/P32/ADR07/2024 and dated 18.02.2025, and subsequent amendments with even number and dated 11.03.2025, 27.03.2025 respectively, the following decisions and information are forwarded herewith for your information and necessary action, please
 - 1.1) Name of the product/Item : **Co-amoxiclav Injection 500mg/100mg Vial**
Co-amoxiclav for injection BP 600mg (Uniclav 600)

SR : **00100904**
 - 1.2) Manufacturer : Navesta Pharmaceutical Pvt Ltd, 107A,
Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka.
 - 1.3) Recommendation of NMRA : Reference is made to the decision of the SAFRESC Committee, dated 13.02.2025, regarding the above product, Accordingly the SAFRESC decision dated 05.07.2024 and 16.07.2024, regarding batch withdrawal of the same has been revised,
2. CEO-NMRA Instruction : **1. The batches using API supplied by Sinopharm Weiqida Pharmaceutical Co Ltd, China, that were manufactured but not fully consumed by 18.07.2024 will be withdrawn. Batches manufactured with the same API that were fully consumed by the date of decision (18.07.2024) will not be subject to withdrawal.**

2. The decision to use only batches manufactured with API supplied by Zhuhai United Laboratories Co Ltd, China, is amended. Batches manufactured using both Sinopharm Weiqida Pharmaceutical Co Ltd, China and Zhuhai United Laboratories Co Ltd, China APIs are permitted for finished product.
However, decision mentioned in No 1 does not affected by this decision.
3. Considering above facts, you are requested the following
 - 3.1) **Make immediate arrangements to submit D/MSD, the unused quantities of following tabled batches, relevant to above product (as detailed 1.1-1.2 above) on or before 11.04.2025.**

- 3.2) As these details are very much important to determine the quality status of the following batches, please be noted that you are responsible for any uninformed quantities of the same batches remaining at your institute.

Item Name	Batch Number	Unused Quantity at the Institute
Inj. Co Amoxiclav 600mg (SR 00100904)	080623AMC1	
	010622AMC1	
	020622AMC1	
	031122AMC1	
	041122AMC1	

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
MSD/Q/P/2024/31(i)		API supplied by Sinopharm, China
MSD/Q/P/2024/44	Product	Withhold
MSD/Q/P/2025/9	Product	Revoke the product withhold decision

Dr. Dedunu Dias.
Director (Acting),
Medical Supplies Division

Dr. DEDUNU DIAS
Director - (Acting)
Medical Supplies Division
No. 2, Baddegama Wimalawansa Thero Mawatha
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. | 6. Secretary/MEC - f.i |
| 7. D/NMQAL - f.i. | | |
| 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. Acct(S)/MSD - f.i. & n.a. | 13. AD/ICT Unit - to publish in MSD web site | |
| 14. AD(P)/MSD - To ensure the sample testing of new batches from NMQUAL, before accepting to MSD | 16. AD(Dispatch)/MSD - f.i. | |
| 15. AD (Stores)/MSD - f.i. | 18. SP / MSD - f.i | 19.HSCO (P3) - f.i. & n.a. |
| 17. All DP/DPDHS - f.i. & n.a | | |
| 20. SCO (S/WH 01)- f.i. & n.a. | 22.MSA-WH (01)/MSD - f.i. & n.a. | |
| 21. SCO (D/WH 01)-f.i & n.a | 24. H/Destruction Unit (MSD) - f.i & n.a. | |
| 23. MO (Technical unit)/MOH-f.i & n.a | | |