

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 Inj 1000mg/200mg Via

1. Re-above, details of the letter received from CEO/ N.M.R.A (NMRA/P32/ADR04/2023 dated 05.04.2024) are given below for your information please.

1.1) Name of the product/ Item	: Co- Amoxiclav Inj 1000mg/200mg Vial Co Amoxiclav for Injection BP 1.2g (Uniclav 1.2)
SR No	: 00100905
1.2) Manufacturer	: Navesta Pharmaceuticals Pvt Ltd ,107A,Nakandala Road,Kindelpitiya, Millewa, Horana.
1.3) N.M.R.A Ref. No	: NMRA/P32/ADR04/2023 dated 05.04.2023
1.4) Recommendation of NMRA	: With reference to the recommendation of Safety and Risk Evaluation Subcommittee held on 04.04.2024, the product mentioned below to be withheld until further notice and the previously withheld batches to be withdrawn from use immediately.

Batches to be Withdrawn:

Batch Numbers	Manuf. Date	Exp Date	LR Number	Order no	PA Order No
360323AMC2	MAR/2023	FEB/2025	-		
560623AMC2	JUN/2023	MAY/2025	39210		
580723AMC2	JUL/2023	JUN/2025	39211		
600723AMC2	JUL/2023	JUN/2025	39212	2023/MSD/N/R/P/00005	MSD/SB08/LM/40/2023

2. CEO-NMRA Instruction : WITHHOLD THE PRODUCT and Withdraw the above mentioned withheld batches from use immediately.

3. Considering above facts, you are requested the following

3.1) To WITHHOLD THE PRODUCT and Withdraw the above mentioned withheld batches 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.

5. Previous Circulars

Circular No	Batch	Decision
MSD/Q/P/2023/35	070123AMC2	Batch Withdraw
MSD/Q/P/2023/36	360323AMC2	Batch Withhold
MSD/Q/P/2023/48	030123AMC2	Batch Withdraw
MSD/Q/P/2023/49	310323AMC2	Batch Withdraw
MSD/Q/P/2023/50	300323AMC2	Batch Withdraw
MSD/Q/P/2023/60	420523AMC2	Batch Withdraw
MSD/Q/P/2023/61	370323AMC2	Batch Withdraw
MSD/Q/P/2023/62	320323AMC2	Batch Withdraw
MSD/Q/P/2023/64	490523AMC2	Batch Withdraw
MSD/Q/P/2023/65	620723AMC2	Batch Withdraw
MSD/Q/P/2023/66	610723AMC2	Batch Withdraw
MSD/Q/P/2023/67	560623AMC2	Batch Withhold
MSD/Q/P/2023/68	580623AMC2	Batch Withhold
MSD/Q/P/2023/69	600723AMC2	Batch Withhold
MSD/Q/P/2023/76	09 batches	Batch Withdraw


Director,
Medical Supplies Division.

Dr. B.A.O. WIJEWICKRAMA
Deputy Director
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** - In the event that obtaining samples from 05 different batches is not possible, to inform D/MSD to send samples from available batches.
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** - To make arrangement to recover the value of relevant quantity from the supplier from relevant batches.
14. AD (Dispatch)/MSD - f.i. 15. AD/ICT Unit - to publish in MSD web site
16. **AD (P I)/MSD** - To ensure that SCO concerned provide the required information to NMQAL
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)**- 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