

Circular No: **MSD/Q/P/2024/30**

My No: MSD/SCU(S)/Cir/2024

Medical Supplies Division

357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10

Tel: (011)2694114/13

24 -07-2024

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 21.05.2024 and NMRA/PA3/ADR04/2023, NMRA/PA3/ADR07/2024 dated 18.07.2024) 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/PA3/ADR04/2023, NMRA/PA3/ADR07/2024 dated 18.07.2024 and NMRA/P32/ADR04/2023 dated 21.05.2024.

1.4) Recommendation of NMRA : With reference to the recommendation of Safety and Risk Evaluation Subcommittee held on 05.07.2024, and 16.07.2024 adopted by the NMRA for the product mention above should be strictly adhered with the instruction given below.

2. CEO-NMRA Instruction : Revoked the Product withhold decision and to withdraw the batches Manufactured using API supplied by Sinochem, China.

- To use only the batches which have been manufactured using the API supplied by Zhuhayi, China.

3. Considering above facts, you are requested the following

3.1) **To Revoked product withhold decision.**

3.2) **To use only following batches which were manufactured using API supplies by Zhuhayi, China according the manufacture's clarification**

Batch Numbers	Manuf. Date	Exp Date	Order no	PA Order No
781123AMC2				
791123AMC2				
801123AMC2	NOV-2023	OCT-2025	2023/MSD/A/R/P/00064	MSD/SB08/LM/40/2023
811123AMC2				
821123AMC2				

3.3) **Do not use the other available batches at your institution. Usable batches will be informed after receiving manufacture's clarification regarding the API supplier.**

3.4) **To withdraw the batches manufactured using the API supplies by Sinochem, China. Withdrawn batches will be informed after receiving manufacture's clarification regarding the API supplier.**

- 3.5) 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
MSD/Q/P/2024/10	Product	Product Withhold and Batches Withdraw


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Cc.