

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 District General Hospitals,  
All Directors General & Base 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 – Metronidazole Injection 500mg in 100mL Bottle**

**MSD ORDER LIST NO: 2023/DON/A/R/P/00055**

**PA Order No: MSD/SB15/DONATION/2023**

1. Re-above, details of the letter received from D/ NMQAL (NDL/C/DU/M7/91 dated 27.05.2024) are given below for your information please.

1.1) Name of the product/ Item	: <b>Metronidazole Injection 500mg in 100mL Bottle</b> <b>Metronidazole Injection IP (0.5% W/V) (METROHIP)</b>
SR No	: 00105203
1.2) Manufacturer	: Hindustan Polyfab , WHO-GMP Certified company, Plot No.12, Industrial Area, Davani, Baddhi, Dist.Solan (HP), 173205, India.
1.3) Batch No	: 0522I002 (0522I002(D-23-40))
1.4) Date of Manufacture	: 09-2022
1.5) Date of Expiry	: 08-2025
1.6) NMQAL LR No	: 39453
1.7) Analytical Report	: <b>Sample dose not conform to IP specification - Description (An almost colourless to pale yellow) - colour variation (colourless to brownish yellow) of the solutions observed among intact bottles.</b>
1.8) NMQAL Recommendation	: <b>To withhold the above batch.</b>

2. CEO-NMRA Instruction : **Withhold the above Batch from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withhold the above Batch 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.

  
Director,  
Medical Supplies Division,  
Rev. Baddegama Wimalawansa Thero Mw;  
Colombo 10.

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. & to inform to the supplier
- 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** - f.i.
- 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 21)** - To send consignment details, storage condition and other relevant details of above product as per the request of NMRA
- 21. SCO (D/WH 21)-f.i & n.a
- 22. MSA-WH (21)/MSD - f.i. & n.a.
- 23. MO (Technical unit)/MOH-f.i & n.a