

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

**REPORT ON FAILING SAMPLE – Prednisolone Oral Solution 5mg/5mL, 60mL Bottle.**

**MSD ORDER LIST No: 2024/SPC/N/R/P/00040**

**PA No: LP/DHS/WD/4018/2024**

1. Re-above, details of the Letter No: NMRA/PA3/QF01/2025 dated 06.01.2025 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item	: <b>Prednisolone Oral Solution 5mg/5mL, 60mL Bottle</b> <b>Prednisolone Oral Solution USP 5mg/5mL</b>
SR	: <b>00701704</b>
1.2) Manufacturer	: <b>Globe Pharmaceuticals Ltd, BSCIC Industrial Estate, Begumgonj, Noakhali, Bangladesh</b>
1.3) Batch No.	: <b>LHA02, LHA03</b>
1.4) Date of Manufacture	: <b>01.01.2024</b>
1.5) Date of Expiry	: <b>31.12.2025</b>
1.6) NMQAL LR No	: <b>40028, 40029</b>
1.7) Failure	: <b>Failure to comply with USP specification for pH test</b>
1.8) Recommendation of NMRA	: With reference to the decision of the Safety and Risk Evaluation Subcommittee dated 02.01.2025 based on the NMQAL report LR 40028, LR 40029
2. CEO-NMRA Instruction	: <b>To withdraw the above batches from use immediately.</b>
3. Considering above facts, you are requested the following	
3.1)	<b>To withdraw the above batches (as detailed 1.1-1.5 above) from use immediately.</b>
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.

  
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. <b>Chairman/SPC</b> – f.i & n.a.	4. DDG(M/S) - f.i.	5.CEO/ NMRA - f.i. & n.a.
6. Secretary/MEC - f.i		
7. <b>D/NMQAL</b> – f.i.		
8. Chief Internal Auditor/ MOH-f.i	9.D/(Stock Verification)/MOH - f.i.	10. DD/MSD - f.i. & n.a.
11. AD (Stores)/MSD - f.i.		
<b>12. Chief Accountant/MSD</b> - To make arrangements to recover the relevant charges.		
<b>13. Acct(S)MSD</b> – To make arrangements to recover the relevant charges.		
14. AD (Dispatch)/MSD - f.i.	15. AD/ICT Unit - to publish in MSD web site	
<b>16.AD (P)/MSD</b> – f.i. & n.a.		
17. All DP/DPDHS - f.i. & n.a	18. SP / MSD - f.i & n.a	19.HSCO (P1) - f.i. & n.a.
<b>20. SCO (S/WH 07)</b> - f.i & n.a	22.MSA-WH (07)/MSD - f.i. & n.a.	23. MO (Technical unit)/MOH-f.i & n.a
21. SCO (D/WH 07)-f.i & n.a		
24. H/Destruction Unit (MSD) - f.i & n.a.		