

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
07-07-2024

Circular No: **MSD/Q/P/2024/28**

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 solu. 5mg/5mL ,60mL Bott.

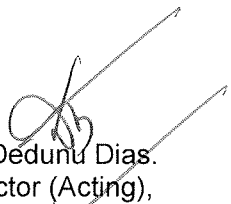
MSD ORDER LIST NO: 2022/SPC/X/R/P/00285

PA Order No: DHS/ICL/MM/297/2022

1. Re-above, details of the letter received from CEO/ NMRA (NMRA/PA13/QF13/2024) dated 09/07/2024 are given below for your information please.
 - 1.1) Name of the product/ Item : **Prednisolone Oral solu. 5mg/5mL ,60mL Bott.
Prednisolone Sodium Phosphate Syrup 5mg/5ml**
 - SR : **00701704**
 - 1.2) Manufacturer : Orbit Pharmaceutical, 22-A/22-B, Meldi Estate, Near Gota Railway Crossing, Gota, Ahmedabad-382 481, Gujarat, India.
 - 1.3) Batch No. : **30602, 30601**
 - 1.4) Date of Manufacture : JUN-2023
 - 1.5) Dare of Expiry : JAN-2025
 - 1.6) NMRA Letter No : NMRA/PA3/QF13/2024 dated 09/07/2024
 - 1.7) Nature of Defect : **Label discrepancy (further analysis was not carried out due to unavailability of standard test procedure)**
 - 1.8) NMRA Recommendation : SAFRESC held on 05.07.2024 recommended to withdraw the above batches.
2. CEO-NMRA Instruction : **Withdraw the above batches from use immediately.**
3. Considering above facts, you are requested the following
 - 3.1) **To withdraw the above 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 NMQUAL.
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.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. | | |
| 14. AD (Dispatch)/MSD - f.i. | 15. AD/ICT Unit - to publish in MSD web site | |
| 16. AD (P)/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 07) - 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 07)-f.i & n.a | 22.MSA-WH (07)/MSD - f.i. & n.a. | 23. MO (Technical unit)/MOH-f.i & n.a |
| 22. H/Destruction Unit (MSD) - f.i & n.a | | |