My No: MSD/SCU(S)/Cir/2023
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
18-05-2023

Circular No: **MSD/Q/P/2023/30**

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 – PREDNISOLONE ACETATE EYE DROP 1%, 5ml DROPPER BOT.

1. Re-above, details of the report received from CEO/ N.M.R.A (Quality log No: 3835) are given below for your information please.

1.1) Name of the product/ Item	: **Prednisolone Acetate Eye Drop 1% ,5ml Dropper Bot. Prednisolone Acetate Ophthalmic Suspension USP 1% W/W, 5ml (IO-PRED-S)**
SR	: **00901001**
1.2) Batch No	: **Product**
1.3) Manufacturer	: Indiana Ophthalmics LLP,135,136,137,G.I.D.C Estate,Wadhwan City 363 035,Dist; Surendranagar,Gujarat,India.
1.4) N.M.R.A Ref. No	: NMRA/P32/ADR02/2023 dated 16.05.2023
1.5) Recommendation of NMRA	: Above product has been withdrawn by NMRA due to serious adverse reaction (Endophthalmitis) with recommendation of SAFRESC held on 11.05.2023. The failing sample report issued by the NMQAL and causality assessment of the ADR reports for the product were considere for the SAFRESC recommendation.
2. CEO-NMRA Instruction	: **To withdraw the above product from use immediately.**

3. Considering above facts, you are requested the following

   3.1) **To withdraw the above product 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.

6. Previous Circulars

Circular No	Batch	Decision
MSD/Q/P/2023/23	Product	Product Withhold
MSD/Q/P/2023/25	N22L16	Batch Withdraw
MSD/Q/P/2023/26	N22L17	Batch Withdraw

Dr. H.M.K. Wickramanayake,
Director
Medical Supplies Division

Dr. H. M. K. WICKRAMANAYAKE
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.
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 05)-** 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 05)-f.i & n.a
22. MSA-WH (05)/MSD - f.i. & n.a.
23. MO(Technical unit)/MOH-f.i & n.a
22. H/Destruction Unit (MSD) - f.i & n.a