Circular No: MSD/Q/S/2024/8

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
29 -06-2024

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

REPORT ON FAILING SAMPLE – Mini Caps (One for each CAPD bag)

1. Re-above, details of the letter no NMRA/MD/QF/13/2023 dated 19.06.2024 received from CEO/ NMRA are given below for your information please.

1.1) Name of the product/ Item	: **Mini Caps (one for each CAPD bag)** **Mini Caps with Povidone Iodine - CAPD (Transfer Set Cap)**
SR	: **14320008**
1.2) Manufacturer	: St. Stone Medical Device Private Limited, A-08, Kuraopokpi, Industrial Estate, Manipur-India.
1.3) Batch No	: **Product**
1.4) NMRA Ref. No	: NMRA/MD/QF/03/2023 dated 19.06.2024
1.5) Nature of the defect	**: Poor quality noted in multiple occasions in multiple nephrology centers.**
1.6) Recommendation of MDEC held on 05.06.2024	: **To withdraw the above Product base on the recommendation of Sri Lanka Society of Nephrology.**
1.7) NMRA Decision	: **Product withdraw**
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/S/2023/13	MCPD06	Batch Withhold
MSD/Q/S/2024/6	MCPD06	Batch Withdraw

Dr. DEDUNU DIAS
Director - (Acting)
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw;
Colombo 10.

Dr. Dedunu Dias.
Director (Acting),
Medical Supplies Division.

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(S)/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 (S) - f.i. & n.a.
20. **SCO/SS(08)-** To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02
21. SCO/SD(1)-f.i & n.a
22. MSA-WH (25)/MSD - f.i. & n.a.
23. H/Destruction Unit (MSD)- f.i & n.a
24. MO (Technical unit)/MOH-f.i & n.a