My No: MSD/SCU(S)/Cir/2023
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
02-05-2023

Circular No: **MSD/Q/P/2023/24**

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 – Propofol Inj IV Infu 50ml Amp./ Vial
MSD ORDER LIST NO:2022/SPC/E/R/P/00768 **PA Order No: LP/DHS/EP/MM/3649/2022**

1. Re-above, details of the report received from CEO/ N.M.R.A (Quality log No: 3842) are given below for your information please.

1.1) Name of the product/ Item	: **Propofol Inj IV Infu 50ml Amp./ Vial (Propofol Injection 500mg/50ml)**
SR	: **01500302**
1.2) Batch No	: **23CPF03**
1.3) Date of Manufacture	: MAR-2023
1.4) Dare of Expiry	: FEB-2025
1.5) Manufacturer	: SP Accure Labs Private Ltd,Pict. No 12,Bictech Park,Phase II,Lalgadi Malakpet (V),Shamirpet (M),Medchal-Malkjgiri (Dist),Telangana (State),500101,India.
1.6) N.M.R.A Ref. No	: NMRA/P32/ADR03/2023 dated 29.04.2023
1.7) Recommendation of NMRA	: Based on the cluster of ADR the batch was withheld by the NMRA as Per the precautionary action.
2. CEO-NMRA Instruction	: **To 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.

Dr. H. M. K. WICKRAMANAYAKE
Director
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw;
Colombo 10.

Dr. H.M.K. Wickramanayake
Director
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** - f.i.
14. AD (Dispatch)/MSD - f.i.
15. AD/ICT Unit - to publish in MSD web site
16. **AD(P II)/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 7)-** 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 7)-f.i & n.a
22. MSA-WH (7)/MSD - f.i. & n.a.
23. MO(Technical unit)/MOH-f.i & n.a