

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
23 -08-2024

Circular No: **MSD/Q/P/2024/34**

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 – Propofol 1% Injection for Intravenous Infusion 50ml Amp/Vial
MSD ORDER LIST NO: 2023/SPC/E/R/P/00142 **PA Order No: LP/DHS/EP/MM/3710/2023**

1. Re-above, details of the Letter No: NMRA/PA3/QF16/2024 dated 22.08.2024 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item : **Propofol 1% Injection for intravenous 50ml Amp/Vial
Propofol for Injection BP 1% W/V 50ml Vial ('CENOFOL')**

SR : **01500302**

1.2) Manufacturer : Armen Pharmaceuticals Pvt. Ltd., Survey No. 494-495, Khambhat-
Petlad Road, At & Post-Bamanva-388580, tal-Khambhat,
Dist-Anand, Gujarat, India.

1.3) Batch No. : **S992302**

1.4) Date of Manufacture : AUG-2023

1.5) Date of Expiry : JUL-2026

1.6) NMQAL LR No : 39444,39366,39487

1.7) Analytical Report : **Failure to comply with BP specifications with respect to the
Bacterial Endotoxin Test.**

1.8) Recommendation of SAFRESC: **To withdraw the above batch from use immediately.**
(held on 21.08.2024)

2. CEO-NMRA Instruction : **Withdraw above batch from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withdraw 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. 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 for the supplier from relevant batches.
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