

Circular No: **MSD/Q/P/2026/25**

To :

DDG/NHSL – Colombo,
DDG/NH – Kandy,
DDG/NH – Galle,
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 – Bupivacaine Hydrochloride Injection 0.5% with Glucose 8% in 4mL Ampoule

1. Re-above, details of the letter NMRA/PV/ADR02/2026 dated 21st August 2026 received from CEO/NMRA are circulated herewith for your information and necessary action, please

1.1) Name of the product/ Item : **Bupivacaine Hydrochloride Injection 0.5% with Glucose 8% in 4mL Ampoule**

Bupivacaine Hydrochloride with dextrose injection USP 5 mg (Bupicaine Heavy)

SR : **01502003**

1.2) Manufacturer : Themis Medicare Ltd, Sector 6A, Plot No 16,17, & 18, IIE, SIDCUL, Haridwar-249 403, Uttarakhand, India

1.3) Batch Details : **All the batches of the same product**

1.4) Reference of NMRA : To the decision of the **Safety and Risk Evaluation Subcommittee (SAFRESC)** dated **17th August 2026**

2. CEO-NMRA Instruction : **Revocation of the product withholding decision**

3. Considering above facts, you are requested the following

3.1) **To revoke the product (as detailed 1.1-1.3 above) withhold decision**

4. Please note: It would be your responsibility, in addition to point 3,

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 this 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 purview.

6. Previous Circulars

Circular No
MSD/Q/P/2026/21

Batch
Product

Decision
Withhold



Director,
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. DDG(M/S) - f.i. |
| 4. Chairman/SPC - f.i & n.a. | 5.CEO/NMRA – f.i. | 6. DD/MSD - f.i. & n.a |
| 7. D/NMQAL – f.i. | | |
| 8. Chief Internal Auditor/ MOH-f.i. | 9.D/(Stock Verific.)/MOH - f.i. | |
| 10. Chief Accountant (Finance) / MSD – f.i. | | |
| 11. Chief Accountant (Supply) / MSD – f.i. | | |
| 12. AD/ICT Unit – To publish in MSD web site | | |
| 13. AD(P)/MSD – f.i. & n.a. | | |
| 14. AD (M&C) – f.i. | | |
| 15. AD (Stores)/MSD - f.i. | 16. AD(Dispatch)/MSD – f.i. | |
| 17. Chairperson / MEC- f.i. | | |
| 18. All DP/DPDHS - f.i. & n.a. | 19. SP / MSD - f.i. | |
| 20. HSCO (P1) - f.i. & n.a. | | |
| 21. SCO (S/WH 07) - f.i. & n.a. | | |
| 22. SCO (D/WH 07)- f.i & n.a. | 23.MSA-WH (07)/MSD - f.i. & n.a. | |
| 24. MO (Technical unit)/MOH- f.i & n.a. | 25. H/Destruction Unit (MSD) - f.i & n.a. | |