

Circular No: **MSD/Q/P/2026/21**

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**

Re-above, details of the letter NMRA/PV/ADR02/2026 dated 03<sup>rd</sup> July 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  
(Bupivacaine Hydrochloride 5mg + Dextrose anhydrous 80mg)  
(Bupivacaine Heavy)**
- SR : **01502003**
- 1.2) Manufacturer : Themis Medicare Ltd, 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 **03<sup>rd</sup> July 2026**, based on the safety concerns raised by the Indian Society of Anaesthesiologists, the above mentioned product withheld from use as a precautionary action in the interest of patient safety
2. CEO-NMRA Instruction : **To withhold the above product from use immediately**
3. Considering above facts, you are requested the following
- 3.1) **To withhold the above product (as detailed 1.1-1.3 above) from use immediately**
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.



Director,  
Medical Supplies Division.

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

Cc:

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|----------------------------------------------|-------------------------------------------|------------------------|
| 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. |                        |