

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division,
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.
Tel: (011)2694114/13
13 -08-2026

Circular No: **MSD/Q/P/2026/23**

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 – Lactulose Syrup 3.0-3.7g in 5mL, 120mL Bottle
Lactulose Oral solution (3.0g-3.7g) / 5mL, 500mL Bottle

1. Re-above, details of the letter NMRA/PA3/QF18/2024 dated 12th August 2026 received from CEO/NMRA are circulated herewith for your information and necessary action, please

1.1) Name of the product/ Item : **Lactulose Syrup 3.0-3.7g in 5mL, 120mL Bottle**
Lactulose Oral solution (3.0g-3.7g) / 5mL, 500mL Bottle
Lactulose Solution BP 667 mg/mL (Medilac)

SR : **00801302 and 00801304**

1.2) Manufacturer : **Mediccom Pvt. Ltd, Sri Lanka**

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

1.4) Reference of NMRA : **To the decisions of the Safety and Risk Evaluation Subcommittee (SAFRESC) dated 20th July 2026, considering the findings of the latest GMP inspections, the status of the corrective and preventive actions (CAPA), and the previous decisions made by SAFRESC on 22nd June 2026 pertaining to Lactulose Solution BP 667 mg/mL (Medilac).**

2. CEO-NMRA Instruction :

- 2.1. All currently withheld batches of Lactulose Solution BP 667mg/ML (Medilac) should be withdrawn**
- 2.2. The Manufacturing Regulatory Division / NMRA will permit the recommencement of manufacturing for the above product only after evaluating the CAPA and achieving satisfactory outcomes**
- 2.3. The Manufacturing Regulatory Division / NMRA will permit the distribution of only those batches of the above product that were manufactured after the approval of a satisfactory CAPA**

3. Considering above facts, you are requested the following

3.1) To Withdraw the above mentioned product (as detailed in 1.1-1.3 above) from use immediately

3.2) Not to accept any newly manufactured batch / batches of the same product to your institution, until further notice

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	Batch	Decision
MSD/Q/P/2024/36	Products with defected labels (SR 00801302)	Withdraw
MSD/Q/P/2025/65	Product	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 – To make arrangements to recover the relevant charges | | |
| 11. Chief Accountant (Supply) / MSD – To make arrangements to recover the relevant charges | | |
| 12. AD/ICT Unit – To publish in MSD web site | | |
| 13. AD(P)/MSD – Not to accept new stocks of the same product until the NMRA approves the distribution of the new batches | | |
| 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 (P2) – Not to accept new stocks of the same product until the NMRA approves the distribution of the new batches | | |
| 21. SCO (S/WH 08) - Not to accept new stocks of the same product until the NMRA approves the distribution of the new batches | | |
| 22. SCO (D/WH 08)- f.i & n.a. | 23.MSA-WH (08)/MSD - f.i. & n.a. | |
| 24. MO (Technical unit)/MOH- f.i & n.a. | 25. H/Destruction Unit (MSD) - f.i & n.a. | |