

Circular No: **MSD/Q/S/2024/2**

My No: MSD/SCU(S)/Cir/2024  
Medical Supplies Division  
357, Ven. Baddegama Wimalawansa Thero Mawatha,  
Colombo 10  
Tel: (011)2694114/13  
**28-02-2024**

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 – NaHCO<sub>3</sub> Powder for Bicarb. HD FMC (Fresenius)**

**MSD ORDER LIST NO: 2021/SPC/N/R/S/00032**

**PA Order No: DHS/S/WW/59/104DC/2021**

1. Re-above, details of the letter NMRA/MD/QF/03/2023/UR dated 22.02.2024 received from CEO/NMRA are given below for your information please.

1.1) Name of the product/ Item : **NaHCO<sub>3</sub> Powder for Bicarb. HD FMC (Fresenius)**  
**“Sodium bicarbonate powder for Hemodialysis (RENABAG)”**

SR No : **14300208**

1.2) Manufacturer : **Renacon Pharma Ltd, 18-KM Ferozepur Road, Opp.**  
**Nishtar Colony, Lahore, Pakistan.**

1.3) Batch No : **9027**

1.4) Date of Manufacture : **08/2021**

1.5) Date of Expiry : **08/2024**

1.6) NMRA Ref. No : **NMRA/MD/QF/03/2023/UR dated 22.02.2024**

1.7) Nature of the defect : **1. During the hemodialysis procedure the bag burst itself.**  
**2. Conductivity fractured during treatment.**  
**3. Blockage of Fresenius Hemodialysis machine.**

1.8) MDEC Decision : **The Medical Devices Evaluation Committee (MDEC) held on**  
**07.02.2024 recommended to revoke the product withdrawal**  
**decision and withdraw the above batch.**

2. CEO-NMRA Instruction : **To revoke the product withdrawal decision and withdraw the**  
**above batch.**

3. Considering above facts, you are requested the following:

3.1) **To revoke the product withdrawal decision and 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 NMQUAL.**

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
6. Previous Circulars

**Circular No**  
MSD/Q/S/2023/2

**Batch**  
Product

**Decision**  
Product Withdraw

  
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.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. <b>D/NMQAL</b> -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. <b>Acct(S)MSD</b> - To make arrangement to recover the value of relevant quantity from the supplier.  |  |                             |
| 14. AD (Dispatch)/MSD - f.i.  | 15. AD/ICT Unit - to publish in MSD web site |                             |
| 16. <b>AD(S)/MSD</b> - To ensure that SCO concerned provide the required information to NMQUAL  |  |                             |
| 17. All DP/DPDHS - f.i. & n.a   | 18. SP / MSD - f.i & n.a                     | 19.HSCO (S) - f.i. & n.a.   |
| 20. <b>SCO/SS(12)</b> - To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02         |  |                             |
| 21. SCO/SD(10)-f.i & n.a  | 22.MSA-WH (54)/MSD - f.i. & n.a.             |                             |
| 23. H/Destruction Unit (MSD)- f.i & n.a   | 24. MO (Technical unit)/MOH-f.i & n.a        |                             |