

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 – NaHCO3 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	: NaHCO3 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 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

6. Previous Circulars

Circular No	Batch	Decision
MSD/Q/S/2023/2	Product	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. 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 from the supplier.	15. AD/ICT Unit - to publish in MSD web site	
14. AD (Dispatch)/MSD - f.i.	18. SP / MSD - f.i & n.a	19.HSCO (S) - f.i. & n.a.
16. AD(S)/MSD - To ensure that SCO concerned provide the required information to NMQAL		
17. All DP/DPDHS - f.i. & n.a		
20.SCO/SS(12)- 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	