Circular No: **MSD/Q/S/2023/10**

My No: MSD/SCU(S)/Cir/2023
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
22-05-2023

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 - Bicarbonate Haemodialysis Concentrate Solution for Bicarbonate Haemodialysis

MSD ORDER LIST NO: 2021/SPM/N/R/S/00002 **PA Order No: 2021/SPM/N/R/S/00002**

1. Re-above, details of the letter received from CEO/NMRA (Quality log No: 3830) are given below for your information please.

1.1) Name of the product/ Item	: **Bicarb. HD Conc. Solu. For Bicarb. HD Bicarbonate Haemodialysis Concentrate Solution for Bicarbonate Haemodialysis (HAEMOCARB - 1.8)**
SR	: **14300201**
1.2) Manufacturer	: Diyatha Pharmaceuticals and Healthcare (Pvt) Ltd , Ja-Ela, Sri Lanka.
1.3) Batch No	: **HDB22K51**
1.4) Date of Manufacture	: OCT-2022
1.5) Date of Expiry	: OCT-2024
1.6) NMRA Ref. No	: NMRA/MD/QF/04/2023 dated 02.03.2023
1.7) Nature of Defect	**: Sample not conform BP Specification for the test for microbial contamination and bacterial endotoxine.**
1.8) NMRA Recommendation	: The Medical Devices Evaluation Committee (MDEC) held on 12.05.2023 recommended to withdraw the above batch from use

2. CEO-NMRA Instruction : **To Withdraw the above batch from use immediately.**

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

   3.1) **To 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 on same item and Manufacturer,

Circular No	Batch No	Decision
MSD/Q/S/2023/4	HDB22L40	Batch Withdraw
MSD/Q/S/2023/5	HDB22M09	Batch Withdraw
MSD/Q/S/2023/6	HDB22M10	Batch Withdraw
MSD/Q/S/2023/7	HDB22L39	Batch Withdraw
MSD/Q/S/2023/8	HDB22L35	Batch Withdraw
MSD/Q/S/2023/9	HDB22L38	Batch Withdraw

Director,
Medical Supplies Division.

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.
14. AD (Dispatch)/MSD - f.i.
15. AD/ICT Unit - to publish in MSD web site
16. **AD(S I)/MSD** - To ensure that SCO concerned provide the required information to NMQAL
17. All DP/DPDHS - f.i. & n.a
18. SP / MSD - f.i & n.a
19. HSCO (S) - 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/PD(10)-f.i & n.a
22. MSA-WH (25) MSD - f.i. & n.a.
23. MO(Technical unit)/MOH-f.i & n.a
22. H/Destruction Unit (MSD) - f.i & n.a