

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
10 -09-2024

Circular No: **MSD/Q/P/2024/37**

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 – Human Immunoglobulin Iv 5-6g Vail

1. Re-above, details of the Letter No: NMRA/PA3/ADR02/2024 dated 09.09.2024 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item	: Human Immunoglobulin Iv 5-6g Vail Normal Immunoglobulin for Intravenous Use BP 5%
SR	: 00603205
1.2) Batch No	: Product
1.3) Manufacturer	: Ichor Biologics Pvt. Ltd, Sy.No,222 P, Turkaply Village, Shameerprtt Mandal, Medchal Malkajgiri Dist-500078, Telangana State, India.
1.4) N.M.R.A Ref. No	: NMRA/PA3/ADR02/2024 dated 09.09.2023
1.5) Recommendation of NMRA	: The NMRA withheld the product based on the recommendation of Safety and Risk Evaluation Subcommittee (SAFRESC) dated 08.09.2023.
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 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.


Dr. Dedunu Dias.
Director (Acting),
Medical Supplies Division,

Dr. DEEJNU 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. & to inform to the supplier
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 - f.i.		
14. AD (Dispatch)/MSD - f.i.	15. AD/ICT Unit - to publish in MSD web site	
16. AD(P 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 (P) - f.i. & n.a.
20.SCO(S/WH 6)- To send consignment details, storage condition and other relevant details of above product as per the request of NMRA		
21. SCO(D/WH 6)-f.i & n.a	22.MSA-WH (6)/MSD - f.i. & n.a.	23. MO(Technical unit)/MOH-f.i & n.a