My No: MSD/SCU(S)/Cir/2022
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
27-05-2022

Circular No: **MSD/Q/P/2022/18**

To :
DDG/NHSL - Colombo
DDG/NH - Kandy
Provincial Directors of Health Services,
Regional Directors of Health Services,
Directors of Teaching Hospitals,
Directors of Specialized Campaigns,
Director, N.I.H.S Kalutara,
MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry

REPORT ON FAILING SAMPLE – Dextrose for IV use 25% , 25ml
MSD Order List No: 2020/SPC/N/R/P/00024 **PA Order No: DHS/AMS/204/2020**

1. Re-above, details of the report received from Director/ NMQAL (Quality log No:3562) are given below for your information please.

1.1) Name of the product/ Item	: **Dextrose for IV use 25% , 25ml**
SR	: **00401103**
1.2) Manufacturer	:AMN Life Sciences Pvt Ltd, 150,Sanjanand Estate,Sarkhej.Tal.City Ahmedabad,Gujarat,India
1.3) Batch No.	: **GL25-12**
1.4) Date of Manufacture	: 01-FEB-2020
1.5) Dare of Expiry	: 31-JAN-2022
1.6) NMRA Ref.	: NMRA/CP/P32/QF22/2021
1.7) Failure / Defect	: Failure of comply with assay test Moulding defect in an ampoule Black floating particles suspected to be fungi in a one ampoule, there was pin-hole damage and only half of the content was in the ampoule. One ampoule of 6ampoules was almost empty and black and white crystalline materials in the empty ampoule. Tendency of damaging the adjacent ampoule when removing one from the attached set of ampoules.
1.8) Recall Committee Recommendation held on 29.04.2022	: **To withdraw the batch.**
1.9) NMRA Recommendation	: **To withdraw the above batch.**
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

Circular No;	Batch	Decision
MSD/Q/P/2021/81	GL25-12	Batch withhold
MSD/Q/P/2021/82	GL25-18	Batch withhold

Dr. CHANDANA WIJESINGHE
(MBBS,MD.PhD)
Director (covering up)
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw;
Colombo 10.

Dr. W. M. C. M. Wijesinghe
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/ SMPSRP-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(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 04)-** To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02
21. SCO(D/WH 04)-f.i & n.a
22. MSA-WH (04)/MSD - f.i. & n.a.
23. MO(Technical unit)/SMPSRP-f.i & n.a