My No: MSD/SCU(S)/Cir/2023
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
01-09-2023

Circular No: **MSD/Q/P/2023/51**

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 – Hydroxyurea (Hydroxycarbamide) Cap. 500mg
MSD ORDER LIST NO: 2021/SPC/N/R/P/00020 **PA Order No: LP/DHS/SP/3025/2021**

1. Re-above, details of the report received from Director/ NMQAL (Quality log No: 4066) are given below for your information please.

1.1) Name of the product/ Item	: **Hydroxyurea (Hydroxycarbamide) Cap. 500mg** **Hydroxyurea Capsules USP 500mg (Joxdramide)**
SR	: **01203501**
1.2) Manufacturer	: Jodas Expoim Pvt Ltd, Plot no.55,Biotech Park, Phase-III, Karkapatla(V),Markook(M),Siddipet(D),Telangana,Pin-502219,India
1.3) Batch No	: **JD20051**
1.4) Date of Manufacture	: 01-NOV-2020
1.5) Dare of Expiry	: 31-OCT-2023
1.6) NMRA Ref No.	: NMRA/P32/QA03/2023 dated 23.08.2023
1.7) Analytical Report	: **Sample does not conform to Manufacture's specification due to softened capsule contains moisturized white crystals in intact packs.**
1.8) Recommendation of NMRA	: **With reference to the recommendation of the Recall Management Committee met on 15.02.2023 and the recommendation of Medicines Evaluation Committee (MEC) on 25.07.2023 (The MEC meeting minutes were confirmed on 22.08.2023. batch number JD20051 withdrawn from use immediately.**
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/2023/3	JD20051	Batch Withhold

Dr. B.A.O. WIJEWICKRAMA
Deputy Director
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw
Colombo 10

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(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 07)-** 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 07)-f.i & n.a
22. MSA-WH (07)/MSD - f.i. & n.a.
23. MO(Technical unit)/MOH-f.i & n.a
22. H/Destruction Unit (MSD) - f.i & n.a