

Circular No: MSD/Q/P/2020/31

My No: MSD/SCU(S)/Cir/2020

Medical Supplies Division

357, Ven.Baddegama Wimalawansa TheroMawatha,
Colombo 10.

24.08.2020



To: DDG/NH-Colombo
DDG/NH-Kandy

All Provincial Directors of Health Services,
Regional Directors of Health Services,
Directors of Teaching Hospitals, PGH/DGH
Directors of Specialized Campaigns,
Director, N.I.H.S., Kalutara,
MOIC/MOH Institutions,
MOIC/Medical Institutions of Line Ministry

REPORT ON FAILING SAMPLE – MEROPENEM INJECTION 1g Vial

1.) Re-above, details of the report received from Director/NMQAL (Quality log No: 2690) are given below for your information please.

- 1.1) Name of the product : Meropenem injection 1g vial /Meropenem for Injection USP 1000mg
SR No : 00102102
- 1.2) Manufacturer : Scott-Edil Advance Research Laboratories & Education Ltd.
Hill top Ind Area, Bhatoli kalan, Baddi, Distt, Solan 173205,
Himachal Pradesh, India
- 1.3) Batch No : Product
- 1.4) NMQUAL LR No : 37751, 37438, 37521, 37662
- 1.7) Analytical Report : Sample is unsatisfactory due to
1. colour variation from white to dark brown colour of powder was observed in some intact vials received at NMQUAL (37438, 37521, 37662, 37751)
 2. Assay-USP-does not conform (37438, 37521)
 3. Constituted solution-USP-does not conform (37521)
- 1.8) NMQUAL Recommendation : To withdraw the product.
2. CEO-NMRA Instruction : To withdraw the above product from use immediately.
3. Considering above facts, you are requested the following:
- 3.1) **To withdraw 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** samples on request to NMQUAL.
4. **Please note:** It would be **your responsibility**,
- 4.1) To coordinate with MSD and arrange to inform withdraw stocks to MSD as detailed in Circular No. WMS-01/ 13 /2009 dated 21.05.2009.
5. i) Please bring the contents of the circular to all concerned in you Province/Region/Institution.
ii) Please note: It is the responsibility of all RDHS to ensure that the copies of this circular is Circulated among all the head of the institutions under your preview.

6. Previous Circulars on same Item and manufacturer

Circular No.	Batch No.	Decision
P-15/24/2019	0328Z001	Batch withdraw
MSD/Q/P/2020/27	0329Z011	Batch withdraw
MSD/Q/P/2020/29	0328Z006	Batch withhold

Director,
Medical Supplies Division

Dr A. T. Sudarshana
Deputy Director
Ministry of Health
Medical Supplies Division,
No. 357, Rev. Bardegama Wimalawansa Maw
Gumbura - Sri Lanka

Cc:

- 1. Auditor General -f.i
- 2. DGHS – f.i.
- 3. Chairman/SPC- f.i.
- 4. DDG (Med Supp)-f.i.
- 5. CEO/NMRA – f.i. & n.a.
- 6. Secretary/MEC – f.i.
- 7. Director/NMQAL – In the event that obtaining samples from 05 different batches as per **“3.2”** is not possible, to inform D/MSD to send samples from available batches.
- 8. Chief Internal Auditor/MOH – f.i.
- 9. Director/ (Stock Verification.)/MOH-f.i
- 10. DD /MSD –f.i
- 11. Acct(S)/MSD – f.i
- 12. AD (P –II /MSD) – **To ensure that SCO concerned provide the required information to NMQAL**
- 13. AD (Stores)/MSD – f.i.
- 14. AD (Dispatch)/MSD-f.i & n.a
- 15. AD / ICT Unit – to publish in MSD web site
- 16. All DP/RDHS-f.i &n.a
- 17.C.P / MSD – f.i & n.a
- 18. HSCO (P)- f.i. & n.a
- 19. SCO (01) – **To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02**
- 20. MSA- WH (01)/ MSD – f.i. & n.a
- 21. MO (Technical unit)/MOH – f.i & n.a