

Circular No: P-57/83/2018

My No: MSD/SCU(S)/Cir/2018
Medical Supplies Division
357, Ven.BaddegamaWimalawanshaTheroMawatha,
Colombo 10.
19.12.2018

To:

All 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 – HYDROCORTISONE HEMISUCCINATE INJECTION 100MG

Order List No: 2018/SPC/L/R/P/00418

PA Order No: LP/CPU/0227/2018

Re-above, details of the report received from Director /NMQAL. (Letter No: NDL/BDU/48/2003 dated 12.12.2018) are given below for your information please.

1.1) Name of the product : Hydrocortisone Hemisuccinate Injection 100mg
(Hydrocortisone Sodium succinate Injection BP 100mg/
primacort-100)

SR No : 00701503 (Previous SR No: 071530)

1.2) Manufacturer : (For) Macleods Pharmaceuticals Ltd,
Atlanta Arcade, Marol Church Road, Andheri(E),Mumbai-400
059. (Manufacturer's name is not indicated on the label)

1.3) Brand Name : "Primacort-100"

1.4) Local Agent : Pettah Pharmacy (Pvt).

1.5) Batch No : C05804

1.6) Date of Manufacture : 01/2018

1.7) Date of Expiry : 12/2021

1.8) Analytical Report as per NMQAL LR No: (36969) : Sample does not conform to BP specification with respect to
the particulate contamination test

1.9) NMQAL 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3.2 To inform the quantity withdrawn from use (Including batch No's and Batch quantity) to Chairman/SPC, No.75, Sir Baron Jayathilake Mw., Colombo 01, with a copy to the undersigned as detailed in para 3.3 below, on or before 05.02.2019 (This information is essential to recover the cost of the item from Supplier, If you fail to provide this information, you are fully responsible for any quantity available with you)

3.3 i) Institutions under Line Ministry, Special Campaigns, Armed Forces and Police should inform the withdrawn quantity directly to Chairman/SPC with copy to D/MSD
ii) With respect to institutions under Provincial Council, relevant RDHS should arrange to collect withdrawn stocks from the institutions at RMSD and inform the full quantity withdrawn (**Not institution wise**) to Chairman/SPC with copy to D/MSD.

3.4) 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 NMQAL.

4. Please note: It would be your responsibility,

4.1) To ensure that all relevant officers do inform the quantity withdrawn from use.

4.2) If stocks are not available, inform

i) Whether stocks received and issued in full

ii) Whether stocks not received

4.3) To coordinate with MSD and arrange to inform withdrawn 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 your 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.

Y.S. Director, Medical Supplies Division
Rev. L. No. 13/2009
Colombo - 10.

Cc:

1. DGHS – f.i. 2. Chairman/SPC - f.i. & n.a. 3.DDG (Med Supp)-f.i.

4. CEO/NMRA – f.i. & n.a. 5. Secretary/MEC – f.i

6. Director/NMQAL –In the event that obtaining samples from 05 different batches as per “3.4” is not possible, to inform D/MSD to send samples from available batches.

7. Chief Internal Auditor/MOH – f.i. 8. Director/ (Stock Verification.)/MOH-f.i

9. DD /MSD –f.i & n.a

10. Acct(S)/MSD – To make arrangement with SPC to recover the value of relevant quantity from the supplier

11. AD (P I-S&D)/MSD -To ensure that SCO concerned provide the required information to NMQAL

12. AD (Stores)/MSD – f.i. 13. AD (Dispatch)/MSD-f.i.

14. AD / ICT Unit – To publish in the web 15. MSA- WH (07)/ MSD – f.i. & n.a

16. S.P/MSD – f.i & n.a 17. HSCO (P)- f.i. & n.a

18 SCO (07)– To send consignment details, storage condition and other relevant details of the above product as per the NDL Form No.02

19. MO (Technical unit)/MOH – f.i & n.a 20. Auditor General / Auditor General's Department -f.i