

Circular No: P-57/83/2018

My No: MSD/SCU(S)/Cir/2018
Medical Supplies Division
357, Ven.BaddegamaWimalawansaTheroMawatha,
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 lable)
- 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 : Sample does not conform to BP specification with respect to
NMQAL LR No: (36969) 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 - 3.2 To **inform** the quantity withdrawn from **use** (Including batch No's and Batch quantity) to Chairman/SPC, No.75, Sir Baron Jayathilake Mw., Colombo 01, with a copy to the undersigned as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 - 3.3) i) Institutions under Line Ministry, Special Campaigns, Armed Forces and Police should inform the withdrawn quantity directly to Chairman/SPC with copy to D/MSD
ii) With respect to institutions under Provincial Council, **relevant RDHS** should arrange to collect withdrawn stocks from the institutions at RMSD and inform the full quantity withdrawn (**Not institution wise**) to Chairman/SPC with copy to D/MSD.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.

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