

**Most Immediate**  
**Through Courier**

**F. No.04-02/2020-QC**  
Government of Pakistan  
**Drug Regulatory Authority of Pakistan**  
Ministry of National Health Regulation Services & Coordination  
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Islamabad, the 03<sup>rd</sup> March, 2020

**[Medical Product Alert]**  
**“Restane (Isoflurane)”**

M/s Taj Medicos  
Chemist & Surgical Stores Shop No.11,  
Sehat Centre ADJ Hotel Regent Plaza,  
**Karachi**

Subject: **COMPLAINT REGARDING USE OF RESTANE (ISOFLURANE)**  
**B.NO.NO219D16- INTERIM REPORT.**

I am directed to refer to the subject cited above and to say that Mr. Sajjad Ahmed Abbassi FID-V Karachi vide letter No.SAA-011/2020 (NTF)-FID-V (K) dated 13-02-2020 wherein he has submitted and inform as under:-

“The FID Karachi in response to a written complaint received from JPMC, Karachi visited and drawn the samples of Restane (Isoflurane) B.NO.N0219D16 purported to be manufactured by M/s Prime Critical Care USA on prescribed Form-3 for the purpose of test/analysis) the said samples were sent to the CDL Karachi on prescribed Form-4 and sealed portion was also sent to the Chairman Drugs Registration Board Islamabad as required under the Drugs Act 1976 the CDL report is still awaited.

M/s Main Pharmacy JPMC Karachi provided the copy of purchase record/bill of M/s Taj Medicos Karachi being the purchase evidence.

M/s Taj Medicos was asked to provide the bill warranty being purchase recorded of said drug however M/s Taj Medicos has submitted the copy of bill/invoice being purchase record but the said purchase record/invoice is not traceable till to date.

The sealed portion of sample were also sent to M/s Allied Distributor (the importer & product license holder in Pakistan) but the said importer has disowned the sealed portion of said drug sample which shows that the suspected drug was supplied through unauthorized source.

In the light of above stated facts and nature of the complaint it is requested that a general public advisory may kindly be issued for stoppage of use of suspected batches of Restane(Isoflurane) (especially the bottles without unit carton) throughout the hospitals in Pakistan for larger public interest.

The investigation of the matter is underway and the complete case will be submitted to the division of QA&LT with due course of time along with the test/analysis reports by the CDL.

02. You are therefore advised to recall all the stocks of suspected batches of Restane (Isoflurane) alert your sales officers/suppliers/ distributors to issue instructions to the pharmacies/hospitals point of sales/purchase/use for the return of suspected stocks of product in question. It shall be ensure that compliance report to this effect should reach to this division within seven (07) days positively under intimation of FID Karachi

**Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmasies Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.**

1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHSR&C, Islamabad.
8. The Director General Health, Government of Punjab.
9. The Director General Health, Government of Sindh.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.
13. The Additional Director DRAP, Lahore.
14. The Additional Director DRAP, Karachi.
15. The Additional Director DRAP, Islamabad.
16. The Additional Director DRAP, Peshawar.
17. The Additional Director DRAP, Quetta.
18. The Chief Drug Inspector Baluchistan.
19. The Chief Drug Controller Punjab.
20. The Chief Drug Inspector Sindh.
21. The Chief Drug Inspector KPK.
22. The Chief Drug Inspector G.B.
23. The Chief Drug Inspector AJ&K.
24. Senior Drug Inspector, ICT, Islamabad.

**Copy to:-**

- 1 The Director, QA&LT, DRAP, Islamabad.
- 2 The Additional Director MIS with request o upload it on official website for larger public interest.
- 3 The FID Karachi for information record and necessary action please.
- 4 M/s Allied Distributors with request to alert your sales officers/suppliers/distributors and issue necessary instructions for stoppage of use of suspected batches of Restane (Isoflurane) (especially the bottles without unit carton) throughout the hospitals in Pakistan for larger public interest
- 5 PA to Minister M/s NHS&RC Islamabad
- 6 PS to CEO, DRAP, Islamabad.
- 7 Office copy

**(Arslan Tariq)**  
**Assistant Director QC-I**