



F.No.13-24/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 16th July, 2020.

[Medical Product Alert]
“Herceptin Injection Solvent Vials-20ml”

M/s Roche Pakistan Limited,
37-B 1st Floor, Block-6,
P.E.C.H.S., P.O. Box 200021,
Karachi.

Subject: **Voluntary Recall of Herceptin Solvent Vials-20ml Due to Glass Particles in Solvent Vials.**

I am directed to refer to your letter No. 042/2020/AT-DRAP dated 25th June 2020 on the subject cited above wherein you have informed regarding the voluntary recall of Herceptin Solvent Vials-20ml due to glass particles in the solvent vials as per following details;

Product Name: Herceptin Injection Solvent Vials-20ml.
Generic Name: Herceptin 440mg
Importer: M/s Roche Pakistan Limited, Karachi.
Batch Number: N7396B04

02. You are therefore advised to recall all the stocks of suspected batch of product, 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 ensured that compliance report to this effect should reach to this division within seven (07) days positively.

(Muhammad Ashfaq)
Assistant Director QC-I

Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, 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 NHR&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: -

- i. The Director, QA<, DRAP, Islamabad.
- ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. The FID Karachi for information record and necessary action please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Office copy.

Assistant Director (QC-I)