



F.No.13-57/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulations & Coordination
Islamabad

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 10th November, 2020.

[Medical Product Alert]
“Azomax 500mg FCT”

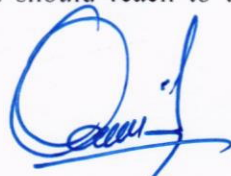
M/s Novartis Pharma (Pakistan) Limited,
15 West Wharf, Dockyard Road,
P.O. Box. 100, **Karachi.**

Subject: **VOLUNTARY PRE-CAUTIONARY RECALL DUE TO POTENTIAL MIX-UP IN AZOMAX 500MG FCT BATCH NO. LJ2L MANUFACTURED BY M/S GSK CONSUMER HEALTHCARE PAKISTAN LIMITED, JAMSHORO FOR M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI.**

I am directed to refer to your letter No. Nil dated 27th October, 2020 wherein you have informed regarding voluntary Recall of your following product due to potential mix-up that can pose potential safety risk to the patients;

Product Name: Azomax 500mg FCT.
Manufacturer: M/s GSK Consumer Healthcare Pakistan Limited, Jamshoro
Batch Number: LJ2L

02. You are therefore advised to recall all the stocks of suspected batch(s) 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.


10.11.2020
(MUHAMMAD ASHFAQ)
Assistant Director QC-I

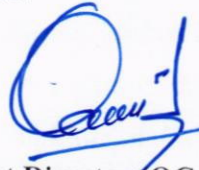
Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.

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 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: -

- 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 Area, FID, DRAP, Karachi for information, record and necessary action please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Office copy.


10-11-2020
Assistant Director (QC-I)