



F. No.03-12/2021-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 04th May 2021.

[Medical Product Alert]

“Klevra Oral Solution”

M/s PharmEvo (Pvt.) Ltd.,
Plot No. A-29,
North West Industrial Zone, Port Qasim,
Karachi.

Subject: **DRUG RECALL of Substandard Klevra Oral Solution, Reg. No. 066831, Batch No. 0N152, Mfg. Date Dec. 2020, Exp. Date Dec. 2022, Manufactured by M/s. PharmEvo (Pvt.) Ltd. Karachi.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.KQ.34/2021 dated 12-03-2021 wherein your following product has been declared as Substandard quality. Details of CDL reports are as under;

S.No.	Name of product	Manufactured by	Reg No.	Batch No.	Mfg. date	Exp. Date	Test Report No. & Date	Result of CDL
01	Klevra Oral Solution	M/s. PharmEvo (Pvt.) Ltd., Karachi	066831	0N152	Dec. 2020	Dec. 2022	No.KQ.57/2021 dated 20-03-2021	Sub-Standard

02. You are therefore directed to recall all the stock of above-mentioned batches of product “**Klevra Oral Solution**” from market & 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. Furthermore, you are directed to submit a compliance report of recall to this division within seven (07) days positively.


(Mehwish Tanveer)
Assistant Director (QC-II)

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 / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
14. The Chief Drug Controller / Inspector Punjab, Sindh, KPK, Baluchistan, AJ&K, GB and ICT.

Copy to:-

- i. The Additional Director, QA<, DRAP, Islamabad.
- ii. The Additional Director, MIS, DRAP, Islamabad.
- iii. Area FID, DRAP, Karachi for information record and necessary action, if any, please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Assistant Director QC-I, DRAP, Islamabad.
- vi. Office copy.


Assistant Director (QC-II)