



F.No.13-67/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulations & Coordination
Islamabad

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 21st December, 2020.

[Medical Product Alert]

Subject: **AVAILABILITY OF SPURIOUS “INJECTION PENRO 1000MG, BATCH NO. PO200017” IN THE MARKET.**

Alert Summary:

This DRAP Medical Product Alert relates to availability of confirmed spurious “Injection Penro 1000mg” identified at retail level in Karachi and reported to Drug Regulatory Authority of Pakistan (DRAP). The product batch, subject of this alert (Table 1) has been declared as spurious by the Federal Government Analyst, Central Drugs Laboratory, Karachi under Section 3(z-b) (i)&(ii) of the Drugs Act, 1976 i.e.

- The product purports to be drug but does not contain the active ingredient of that drug &
- The product purports to be the product of a manufacturer, place or country of whom or of which it is not truly a product.

Table 1: Product subject of DRAP Medical Product Alert No. F.No.13-67/2020-QC

Product Name	Injection Penro 1000mg
Stated Manufacturer	M/s Bosch Pharmaceuticals (Pvt.) Ltd., Karachi
Batch Number	PO200017
Mfg. Date	05-2020
Exp. Date	04-2023

The following facts regarding the subject product batch, have also been transpired by the Federal Government Analyst, Central Drugs Laboratory, Karachi;

- **Printing color of subject batch sample was black whereas reference pack was of grey color**
- **Diluent used with subject batch sample, was of KPL, Batch No. 402 & Batch No. WI20041 whereas genuine manufacturer used their own diluent in reference pack.**
- **PENRO brand name on subject batch sample was written with spreading ink whereas the printing on reference pack was clear and of good quality.**

- **The genuine manufacturer of the product i.e., M/s Bosch Pharmaceuticals (Pvt.) Ltd., Karachi has also disowned the subject product batch claiming that this batch No. has never been allotted to any batch of Injection Penro 1000mg.**

Advice to Provincial Health Authorities and the Public:

DRAP requests increased vigilance within the supply chains of countries likely to be affected by this spurious products batch. Increased vigilance should include hospitals, clinics, health centers, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If anyone is in possession of the above stated product batch, please do not use. If anyone has used this spurious product batch, or if anyone suffer an adverse reaction/event having used this product batch, it is advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

All medical products must be obtained from licensed, authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

(HAFIZ SANAULLAH BABAR)
Assistant Director (QC-III)

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/Officer In-charge DRAP, Islamabad, Lahore, Karachi, Peshawar and Quetta **with the request to direct field force under your administrative control to conduct the market survey & submit the report to this Division.**
14. The Chief Drug Controller/Inspector Punjab, Sindh, KPK, Baluchistan, ICT, AJ&K and GB.

Copy to: -

- i. The Additional Director, QA<, DRAP, Islamabad.
- ✓ ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. PS to CEO, DRAP, Islamabad.
- iv. Office copy.


Assistant Director (QC-III)