



F. No. 04-46/2024-DD(QA&LT-III)  
Government of Pakistan  
**Drug Regulatory Authority of Pakistan**  
Quality Assurance and Laboratory testing division,  
Prime Minister's National Health Complex, Park Road, Islamabad  
\*\*\*\*\*

**MOST URGENT**

Islamabad, the 25<sup>th</sup> October, 2024.

## **ADVISORY**

Subject: **IMPORT OF UNREGISTERED / UNAVAILABLE THERAPEUTIC GOODS BY INSTITUTIONS / HEALTHCARE FACILITIES**

The Drug Regulatory Authority of Pakistan (DRAP), as the National Medicine Regulatory Authority is mandated to regulate therapeutic goods through various functions with the mission to ensure access to safe, quality and efficacious therapeutic goods in line with national laws and international best practices. Healthcare service delivery is dependent on the collaborative working of the different stakeholders with the ultimate objective of optimum patient care.

2. Recently, Adverse Drug Reactions (ADRs) have been reported in a healthcare facility following the use of Avastin injection. Investigations have confirmed that these injections were falsified, and same has been endorsed by the market authorization holder of the product i.e. M/s. Roche Pakistan Limited, Karachi.

3. Apropos, all Hospitals/Health care facilities are required to procure registered / enlisted therapeutic goods exclusively through authorized distributors or sellers of the products. In instances where an essential therapeutic good is either unregistered or unavailable due to any reason, such products can be imported by the hospital or institution in compliance after approval of DRAP as per SRO 134(I)/2021 dated 09<sup>th</sup> February 2021 (In case of unregistered/unavailable medicinal products) and under 24(d) of Medical Device Rules 2017 (In case of unregistered/unavailable medical device). Additionally, detailed guidance on the importation of unregistered or unavailable drugs for hospital or institutional patient use can be found online at DRAP's website via the following link <https://www.dra.gov.pk/wp-content/uploads/2022/04/Import-and-Export-guidelines-Final.pdf>

4. Furthermore, all adverse reactions experienced with the use of any product should be reported to the National Pharmacovigilance Centre (NPC) DRAP, using Adverse Event Reporting Form available at following link <https://www.dra.gov.pk/wp-content/uploads/2022/07/Suspected-Adverse-Reaction-Reporting-Form-for-Health-Care-Professionals.pdf>. Additionally, complaints regarding quality attributes or any other related issue can be reported to DRAP online on following link <https://www.dra.gov.pk/safety-information/safety-communication/report-a-problem/>



5. In case of any further queries, it is requested to contact the undersigned at [dir.qa@dra.gov.pk](mailto:dir.qa@dra.gov.pk)

**Dr. Obaidullah**  
Director (QA&LT)

**Distribution:**

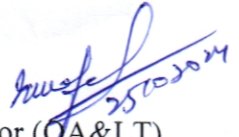
- i. The Secretary, SH&ME Department, Government of Punjab, Lahore.
- ii. The Secretary, Health Department, Government of Sindh, Karachi.
- iii. The Secretary, Health Department, Government of Khyber Pakhtunkhwa, Peshawar.
- iv. The Secretary, Provincial Health Directorate, Government of Balochistan, Quetta.
- v. The Secretary, Department of Health, Government of Gilgit Baltistan, Gilgit.
- vi. The Secretary, Health Department, Government of Azad Jammu & Kashmir, Muzaffarabad.
- vii. JS (Hospitals), M/o National Health Services, Regulations & Coordination, Islamabad.
- viii. The Medical Directorate, General Headquarters (GHQ), Rawalpindi.
- ix. Executive Director, PIMS, Islamabad.
- x. Executive Director, Polyclinic Islamabad.
- xi. Executive Director, Federal General Hospital, Islamabad.
- xii. Medical Director, CDA Hospital, Islamabad.
- xiii. District Health Officer, Islamabad Capital Territory, Islamabad
- xiv. Director General Health Azad Jammu & Kashmir, Muzaffarabad.
- xv. Director General (DG) Health Services Gilgit Baltistan, Gilgit.
- xvi. Chief Executive Officer, Islamabad Healthcare Regulatory Authority, Islamabad.
- xvii. Chairperson, Punjab Healthcare Commission, Lahore.
- xviii. Chief Executive Officer, Sindh Healthcare Commission, Karachi.
- xix. Chief Executive Officer, Khyber Pakhtunkhwa Health Care Commission, Peshawar.
- xx. Chairperson, Balochistan Health Care Commission, Quetta

With request to disseminate the information to Public sector healthcare facilities for implementation.

With request to disseminate the information to Private sector healthcare facilities for implementation.

**Copy for information to:**

- i. P.S. to CEO, DRAP, Islamabad.
- ii. Director MIS DRAP Islamabad – with request to upload the advisory on DRAP's website.
- iii. Office Copy.

  
Director (QA&LT)