



TRANSPARENCY INTERNATIONAL - PAKISTAN

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Mr Ali Amin Khan Gandapur
Chief Minister Khyber Pakhtunkhwa
CM Secretariat, Peshawar

Subject: Complaint Against Allegations of Lack of Regulation and Availability of Sub-Standard, Spurious, and Unregistered Drugs Available in the Market

Dear Sir,

Transparency International Pakistan has received a complaint against the allegations of lack of regulation and availability of sub-standard, spurious and unregistered drugs in the market.

The complainant has made the following allegations.

That;

1. A large number of nutraceuticals and alternative medicines are sold in the market without adherence to rational formulation standards, validation of their analytical methods and in violation of labelling requirements.
2. A recent incident at the Punjab Institute of Cardiology, where expired cardiac stents were allegedly administered to cardiac patients, underscores the urgent need to regulate medical devices more strictly.
3. Despite the clear responsibilities assigned to drug inspectors under the Drug Act, 1976—including oversight of alternative medicine manufacturing facilities—drug inspectors have failed to ensure inspection or regulatory oversight.
4. Additionally, a significant quantity of unregistered veterinary medicines, both imported and locally manufactured, continues to circulate in the market which poses a serious threat to livestock health and constitutes a violation of national drug laws.
5. Pharmacies / Medical store are major source for the sale of unregistered and sub-standard drugs especially in rural areas, where opportunist exploit the system by selling such type products to innocent people. Moreover, medical stores selling veterinary medicines are often overlooked by the inspectors. Thus, encouraging selling of spurious drugs.
6. Approximately 40-45 thousand medical stores / pharmacies are all over the Pakistan, only regular and critical inspection of pharmacies / medical stores can improve the situation and pose serious threat to spurious drugs manufacturers which is currently neglected in most of the cases.
7. Imported alternative medicines / veterinary products / nutraceutical products are often ignored during the medical store visits which encourages the sales of spurious drugs.

Transparency International Pakistan Comments

Transparency International Pakistan has reviewed the allegations of the complaint. Prima facie, the allegations seem correct. Following are TI Pakistan's comments:

1. Comprehensive sampling and testing of all categories of drugs, including human pharmaceuticals, nutraceuticals, alternative medicines, and veterinary drugs, should be carried out to ensure quality and compliance.
2. Any violation of labelling rules (missing of name of manufacturer, registration number, batch number, manufacturing date and expiry date) should be dealt in accordance with the rules.



3. Medical devices for which registration extensions have lapsed, or which are expired or unregistered, must be identified, and legal action should be taken against the responsible institutions or individuals in accordance with applicable laws and regulations.
4. All nutraceutical and alternative medicine manufacturing units must be inspected to verify the presence of functional laboratories and qualified quality control personnel. In cases of non-compliance with GMP standards, appropriate legal action should be taken under the applicable rules.
5. Provincial Quality Control Board (PQCB) meetings must be conducted regularly to address pending regulatory issues and monitor market conditions effectively, as per section 11 (5) of the Drugs ACT: 1976, which confers the following powers and functions of the Provincial Quality Control Board, namely: -

(a) to inspect any premises where any drug is being, or is to be, manufactured or sold and to recommend to the appropriate authority the cancellation or suspension of the licence to manufacture or sell drugs granted to any person who is found to be contravening, or to have contravened, any of the provisions of this Act, or the rules;

(b) to scrutinize the reports of Provincial Inspectors in respect of contraventions of this Act and reports of the Government Analysts in respect of drugs sent to them by the Provincial Inspectors for test and analysis and issue instructions to the Inspectors as to the action to be taken on such reports;

6. The provincial government should align their actions with the framework provided under the DRAP Act, 2012.

Transparency International Pakistan Recommendations

Transparency International Pakistan requests the Chief Minister Khyber Pakhtunkhwa to examine the allegations of the complaint, and if found correct, issue directives for action against the sub-standard, spurious, and unregistered drugs available in the market, in violation of DRAP Act 2012, and the Drugs Act 1976 as well as directives for drug inspectors to ensure effective enforcement in compliance with DRAP Act 2012, and the Drugs Act 1976.

Transparency International Pakistan is striving for across-the-board application of the Rule of Law, which is the only way to stop illegal practices and achieve Zero tolerance against corruption.

Regards

Advocate Daniyal Muzaffar,
Trustee/Legal Advisor
Transparency International Pakistan

Copies forwarded for the information with a request to take action under their mandate to:

1. PSPM, PM House, Islamabad.
2. Minister, Ministry of Health, Govt of KP, Peshawar.
3. Secretary, Ministry of Health, Peshawar.
4. CEO, DRAP, Islamabad.
5. Chairman Pakistan Pharmacist Association.
6. Registrar, High Court of Khyber Pakhtunkhwa, Peshawar.



Note:

This is to clarify that Transparency International Pakistan is not a complainant, it acts as a whistleblower and operates under Article 19-A, of the Constitution of Pakistan which gives the right to public to know how government is being run by public officers. Article 19-A makes the right to access of information pertaining to a public authority a fundamental right, and a three-member bench in the case of Mukhtar Ahmad Ali vs the Registrar, Supreme Court of Pakistan, Islamabad, headed by Chief Justice Qazi Faez Isa in the landmark judgment on 16 October 2023, in CP No. 3532/2023, has declared that

“What previously may have been on a need-to-know basis Article 19A of the Constitution has transformed it to a right-to-know, and the Access to information is no longer a discretion granted through occasional benevolence, but is now a fundamental right available with every Pakistani which right may be invoked under Article 19A of the Constitution”