

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan
(Legal Affairs Division)
Prime Minister's National Health Complex, Park Road, Islamabad
☎☎☎☎☎☎

File No. 11-4/2025-LA

Islamabad, the 25th February, 2026.

✓ **Mr. Daniyal Muzaffar, Advocate**
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Transparency International Pakistan,
Plot 72-F/2, 1st Floor 9th Street, Jami Commercial, Phase 7, DHA,
Karachi.

**Subject: COMPLAINTS AGAINST ALLEGATIONS OF DELAY IN
REGISTRATION AND LICENSING APPROVALS OF MEDICAL
DEVICES BY MEDICAL DEVICES AND MEDICAL COSMETICS
DIVISION DRAP IMPACTING THE LOCAL IMPORTERS AND
PATIENTS.**

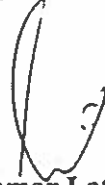
Please refer to your letter number TL2026/0213/1A dated 13.02.2026 regarding captioned subject. Drug Regulatory Authority of Pakistan (DRAP) denies these allegations being factually incorrect.

2. Over the past one year, DRAP has significantly strengthened its internal processing workflows and monitoring systems to ensure timely disposal of applications in general and medical devices in specific. Currently about 70% of DRAP's regulatory processes are completely digitized (licensing, registration, pricing, import and export of pharmaceuticals and biologicals, lot release of vaccines, allocation of controlled drugs, licensing and registration of medical devices) and remaining digitization will be completed tentatively by June 2026. These steps have resulted in better digital workflow, tracking of application, internal performance reviews, improved coordination among applicants and regulators, measurable efficiency gains and ultimately led to better and earliest access to medicine and medical devices with significant reduction in approval timelines. It is also pertinent to note that due to such significant improvements in regulatory performance, honorable Prime Minister of Pakistan has conferred, "*Reforms Champion Award*" to DRAP in December 2025.

3. Since the launch of online portal for Medical Devices applications in July 2025, Medical Devices Board (MDB), DRAP has so far decided 4196 applications and average time for disposal of these applications is 21.8 business days, which was previously invariably months and years. Furthermore, manual applications submitted prior to digitization have been systematically reviewed / assessed and about 5066 manual applications have been considered by MDB by convening weekly meetings and about 2900 approval letters have already been issued. Rest of the applications were found to be deficient requiring regulatory information, clarifications and statutory compliance prerequisites related to the applied products. Such requirements are

mentioned in decisions of MDB and available on DRAP's website and are being processed after provision of requisite information by applicants. It is important to highlight that these outcomes have been achieved through process optimization and dedicated efforts of same number of officers and staff with improved service delivery standards and better teamwork.

4. DRAP remains fully committed to transparency, regulatory efficiency, achieving WHO and other international accreditations and facilitation of stakeholders while ensuring compliance with applicable laws and quality standards being custodian of public health. DRAP is currently recruiting additional technical personnel and strengthening IT infrastructure to further improve service delivery standards and enhance institutional capacity. Any assertion that the DRAP is not performing does not reflect the current operational realities or the significant progress made in reducing backlog and decision timelines. If the complaint you have received is about a specific company or product, please inform DRAP of the resolution of complaint within the applicable regulatory framework. The Authority welcomes constructive engagement and remains open to sharing operational updates to ensure informed understanding of its regulatory efforts.



(Aamar Latif)
Director (Legal Affairs)

Copy to:

1. PSPM, PM House Islamabad;
2. Federal Minister for National Health Services, Regulations and Coordination, Islamabad;
3. Federal Secretary, Ministry of National Health Services, Regulations and Coordination, Islamabad;
4. Registrar, Supreme Court of Pakistan; and
5. Director Reforms, Board of Investment, Islamabad.