དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བ་ལྟན་ཁག་ འབྲུག་བཟའ་ཚས་དང་སྨན་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY

DRA/D1/12-GEN-MD/2022-2023/ 456 **07 March 2023**

Regulatory Notification

Drug abuse detection is crucial in a variety of societal contexts, including sports, suspicious deaths, violent crimes, travel, and workplace safety. Analytical findings should be accurate, trustworthy, and tenable. Drug of Abuse (DoA) test kits are nearly often used for clinical and medico-legal preliminary assessments of misused drugs, and should be used as the basis for reporting a positive drug discovery in a biological specimen. The access to subpar DoA test kits may lead to false positive results and should be prohibited. As DoA test kits are classified as medical products under the Medicines Act of the Kingdom of Bhutan, 2003, the Bhutan Food and Drug Authority (BFDA) is entrusted with overseeing their regulation including registration of the kits. Thus, the BFDA will institute the regulation of kits for drug abuse testing that identifies the following substances:

1. Amphetamine(AMP);
2. Benzodiazepine(BZO);
3. Cocaine (COC);
4. Ketamine (KET);
5. Methamphetamine(MET);
6. Methylene Dioxymethamphetamine (MDMA);
7. Opiates (OPI);
8. Propoxyphene (PPX);
9. Tetrahydrocannabinol (THC) and
10. Tramadol (TRA)

DoA test kits are classified as class C medical devices as per the classification rule set by global harmonization task force therefore, the applicants are required to adhere to the notification DRA/D1/31-Med-Device/21-22/107 issued on 31st August, 2022 and register DoA test kits accordingly.

This notification is issued for immediate compliance.

For further clarification and queries contact BFDA officials at +975-02-337074/337075.

DIRECTOR