ངན་སྐྱོན་བཀག་སྡོམ་ལྷན་ཚོགས།
ACC
ANTI-CORRUPTION COMMISSION

ངན་སྐྱལ
(Issue 2)

Highlighting anti-corruption matters for you to Know, Understand and Act!

Advisory on Medicine Import Licensing and Monitoring

Background

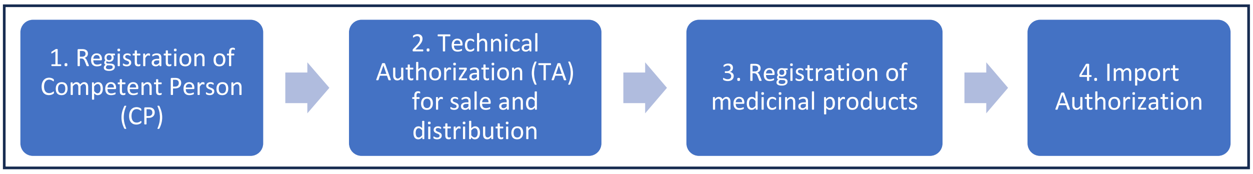
A country's medical and health system is of vital importance as a robust health system ensures citizens' access to efficient, affordable and quality healthcare services. However, health systems, in any country, are also prone to corruption. For instance, in Bhutan, as per the National Corruption Barometer Survey 2023 carried out by BTI, out of 20 different public services, the health services were perceived to be the most susceptible to corruption. Similarly, as per the ACC's National Integrity Assessment 2022, the score for perception of corruption in the health sector, by the service users, was a score of 6.32, which falls in the *need improvement* category. Therefore, it is crucial that all possible intervention efforts, big and small, are explored and adopted to combat and prevent corruption in the health sector.

In this regard, ACC recently completed a system study on the *Medicine Import Licensing and Monitoring* function of the erstwhile Drug Regulatory Authority, now the Medical Products Division under the Bhutan Food and Drug Authority (BFDA). The study identified some potential corruption risks that are being sensitized to prompt corruption prevention initiatives proactively by the relevant stakeholders. Further, this prevention advisory highlights the study findings and is aimed at advocating the risks and possible mitigation measures pertaining to the import of medicines and purchases from pharmacies.

These are by no means exhaustive and stakeholders are strongly encouraged to implement other additional initiatives as they find technically appropriate and necessary. These marginal but cumulative efforts from all stakeholders would certainly make a positive impact and contribute towards ensuring the quality, safety, and efficacy of medicinal products in the country as enshrined in the Medicines Act of the Kingdom of Bhutan 2003.

The mitigation measures in this advisory have been conceived taking into account the four processes involved in the import of medicinal products, as depicted in *Fig. 1* below.

Fig. 1: Process for import of medicinal products



Over the years, the Medical Products Division has instituted several guidelines, standards, and online services to improve their services, including CP and TA registration and import authorization going online (G2C services). Nonetheless, some areas in the existing medicine import licensing and monitoring system need strengthening.

Risks and Mitigation Measures

The risks and mitigation measures presented in *Table 1* below pertain solely to medicine import licensing and monitoring. The BFDA and relevant stakeholders are recommended to implement these suggested mitigation measures and other proactive initiatives to prevent the identified risks.

Table 1: Risk area, risks and mitigation measures

Risk Area	Risks	Mitigation Measures
Conduct of Competency Examination - Questions are prepared by the Registration Committee and retained in question banks. - The focal person selects questions from the question bank and puts up to the Drug Controller. - The Drug Controller selects the final question set to be used for the exam.	• Non-involvement of the Registration Committee in selecting the final questions for the exams can lead to biasedness and conflicts of interest. • No requirement or practice of declaring conflicts of interest at any stage. • Likelihood of leakage of questions and conflict of interest. • Lack of mechanism to ensure anonymity of the applicants. This poses risk of unethical practices by evaluators during evaluation.	• The Registration Committee should be responsible for selecting the final questions since it is currently done by the focal person and drug controller only. • Institute the practice of declaring and managing conflict of interest during the selection of questions and evaluation of exam papers. • Introduce a code/index numbering mechanism to institute a system to maintain anonymity of the applicants.
Collection of fees for product registration - The medicinal product registration services, unlike the services for competent persons, technical and import authorizations, is not incorporated in the G2C system.	• Fees for product registration are collected in cash or in person posing potential risk of embezzlement. • The only measure, currently in place, is maintenance of the record of payments (Hard copies of receipt).	• Facilitate payment of all types of fees as far as possible through online payment systems. • Ensure the collected fees are continued to be deposited in the government account in a timely manner.
Inspection/Monitoring	• Risk of bribery pertaining to reduction or waiving-off of fines/penalties during inspection/monitoring. • Risk of abuse of function in terms of fines and penalties on family members, relatives, friends, etc. • Risks of false TADA claims.	• Strengthen ethics and integrity through: i. Strict enforcement of the code of ethics and conduct for inspectors as per the Inspection Guideline 2018; ii. Declaration and management of conflict of interest; and iii. Training and awareness on ethics and integrity.
Sale of unregistered medicinal products in pharmacies	• Sale of unregistered, spurious or substandard medicinal products pose serious threat. Seizure of products and fines appear to have no deterrent effect as the trend has been observed over last three years. • This indicates a lack of proper inspection at the point of entry.	• Review existing fines and penalties. • Consider canceling the TA at the first offense itself. • Highlight penal provisions on the Import Authorization to raise awareness. • Strengthen monitoring at point of entry to prevent entry of unregistered, spurious or substandard medicinal products into the country.

Precautionary Measures for the General Public

Some precautionary measures for the general public with regard to purchase of medicinal products and reporting potential issues include:

- **Purchase Medicinal Products from Registered and Licensed Pharmacies:** Before making a purchase, check the pharmacy's license or registration certificate, which is required to be displayed prominently. The list of registered wholesalers and retailers is available on BFDA's website.

- **Report Adverse Reactions:** If you experience unexpected side effects or adverse reactions from a medication, promptly report them to the BFDA. Reporting helps monitor medication safety and protect others.

- **Stay Informed**: Be updated and informed about the regulatory notifications issued from time to time by the BFDA on matters such as unauthorized sources, recalled medicinal products, cancellation of authorization for certain medicines, etc.

- **Reporting Wrongdoings and Corruption:** The general public has an important role in deterring and preventing corruption by reporting any wrongdoings/unethical practices by pharmacies to relevant agencies such as the BFDA. You can contact ACC through the following reporting channels:

  i. Telephone no. +975-02-334863
  ii. Juenlam ACC (WeChat: 17123412 or WhatsApp: 17123413)
  iii. Fax no. 334865
  iv. Email: complaints@acc.org.bt
  v. Walk-in any ACC offices (Thimphu, Bumthang, Phuentsholing and Trashigang)
  vi. Download and install myACC app which is available on App Store as well as Google Play Store to report corruption and track the status of complaints.

  The Anti-Corruption Commission affirms its commitment to preserving the anonymity and confidentiality of the complainants.

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