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THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR

MINISTRY OF HEALTH

ZANZIBAR FOOD AND DRUGS BOARD

COMPLIANCE AND ENFORCEMENT POLICY

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P.O.Box 3595, Mnazi Mmoja Area, Kaunda Road, Zanzibar
Tel: + 255 24 2233959-, Fax:+ 255 24 2233959, Website www.zfdb.go.tz, E mail: food@zfdb.go.tz

Mission

To protect and promote public health by ensuring quality and safety of food, drugs, cosmetics and medical devices.

Vision

To provide the best regulatory services of food, drugs and cosmetics in East Africa by 2020.

Philosophy

ZFDB is a gender sensitive organization which strives to offer quality regulatory services in the pursuit of protecting public health and environment by using competent and dedicated staff.

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1.0. BACKGROUND

Responsibility for quality and safety of food, drugs, herbal drugs, cosmetics and medical devices is shared among food and healthcare professionals, industry, consumers, government, and other stakeholders. Laws are in place in order to promote the safety of products to which Zanzibarians have access.

The mandate of ZFDB is to control the quality, safety, and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices by minimizing health risk factors to Zanzibarians while maximizing the safety provided by the regulatory system for such products and promoting conditions that enable Zanzibarians to make healthy choice and providing information so that they can make informed decisions about their health. The ZEDB administers its legislative and regulatory frameworks using risk management and scientific evidence to maximize the safety and quality of products available to Zanzibarians.

ZFDB is responsible for 'National-wide compliance and enforcement activities' enabling consistency of approach across the spectrum of regulated products. The Board's core functions are compliance monitoring, and compliance verification, supported by establishment licensing of food manufacturing premises, drugs, herbal drugs, cosmetics, medical devices, and laboratory analysis.

1.1. Purpose

This document provides the staff and stakeholders of the Zanzibar Food and Drugs Board, as well as the public, with guiding principles for the fair, consistent, uniform applications and enforcement of Zanzibar Food, Drugs and Cosmetics Act, 2006 and it's associated Regulations under the statutory power of the Board.

The document clearly describes the role of ZFDB in delivering a national compliance and enforcement program for all products under its mandate. The policy also describes the role of regulated parties, and the Board's relationship with consumers, food and health care professionals in relation to products and activities it regulates.

1.2 Scope

The policy applies to all products regulated by the Board as defined under section 3(1) of the Zanzibar Food, Drugs and Cosmetics Act No. 2 of 2006. This includes food, drugs, herbal drugs, cosmetics and medical devices.

1.3 Definitions

Act: The Zanzibar Food, Drugs and Cosmetics Act. No. 2 of 2006.

Board: The Zanzibar Food and Drugs Board or the acronym ZFDB.

Compliance Monitoring: Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the Zanzibar Food, Drugs and Cosmetics Act, 2006 (herein to be referred to as the Act) and its associated Regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product sampling program.

Compliance Verification: Actions taken to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act and its associated Regulations. This includes actions such as information gathering either off-site or via on site visits.

Compliance: The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with legislative or regulatory requirements.

UIE: Unit of Inspection and Enforcement.

Enforcement: Actions that may be taken to induce encourage or compel compliance with the Act and its associated Regulations.

Inspection: On-site monitoring and assessment against the applicable requirements of the Act and its associated Regulations. Inspection is routinely conducted on the predetermined cycle or as required to assess compliance.

Inspector: Any person designated for doing inspection for the purpose of the enforcement of the Act under section 106(1) (a) - (c).

Marketing authorization: A legal document issued or approved by the Board, authorizing the sale of a regulated product based on the quality and safety requirements of the Act and its associated Regulations.

2.0. POLICY STATEMENT

The following guiding principles govern the Board in the application of the Act and its associated Regulations made there under.

2.1. Transparency

The *Compliance and Enforcement Policy* is a public document. Consistent with and in the spirit of access to information, the Board makes information on compliance and enforcement activities available to the public.

2.2. Fairness

The *Act and Regulations* are applied in fair equitable manner.
The Board follows a predictable, uniform, and national approach to enforcement in Zanzibar for all of ZFDB's regulated products, irrespective of where or by whom these products are sold, advertised, fabricated, processed, packaged/labeled, imported, distributed, tested or stored. The Board takes a non-discriminatory and unbiased approach to its activities.

2.3. Risk Management

The Board's activities are guided by the *Board Decision Making Framework*. Risk assessment and risk management are important components of this framework. Risk can manifest in a variety of ways, such as sale of a product in the absence of market authorization. The Board's activities are structured to achieve the greatest impact and efficiency in addressing the identified risks.

2.4. Commitment to Quality

The Board's commitment to quality is demonstrated through the integration and promotion of quality management principles (according *ISO 9001:2008* standard) within the organization. The Board quality objectives are uniformity in fulfilling our compliance and enforcement responsibilities.

2.5. Qualified and Competent Staff

Board employees receive training to ensure they are qualified and knowledgeable of the products, activities being regulated and the environment in which they are to apply such

knowledge.

2.6. Responsibilities

It is the Board's responsibility to conduct compliance and enforcement activities in accordance with this policy. Inspectors' powers are described under section 107(1) (a)-(g) of the Act.

The maintenance and enhancement of the quality and safety is a responsibility that is shared among government and industry, consumers, food and healthcare professionals and their respective associations.

Regulated parties that market food, drugs, herbal drugs, cosmetics and medical devices have the primary responsibility for the safety of any product they sell, manufacture, import or distribute to the Zanzibarian public. These regulated parties must comply with the all Zanzibarian legislative and regulatory requirements.

Consumers have a responsibility for the maintenance of their health and the safe use of marketed and regulated products. Consumers should us manufactured products according to the manufacturer's instructions. In addition, consumers are asked to inform the ZFDB of any problems that they encounter (hazards, adverse reactions, malfunctions, and non-compliance) through the use of food, drugs, herbal drugs, cosmetics and medical devices.

Food and healthcare professionals are encouraged to inform the ZFDB of any problems they encounter (hazards, adverse reactions, malfunctions, and non-compliance) that may be related to food, drugs, herbal drugs, cosmetics and medical devices. The primary responsibility for safety of consumers lies on one hand with the drugs or medical devices manufacturer and the dispensing pharmacist and on the other hand with the food manufacturer and the food technologist. Food technologist and pharmacist have professional standards and obligations and it is the responsibility of professional regulatory bodies (such as Zanzibar Medical Store) to ensure that these professional standards are met. Food and Drugs manufacturers and importer as well as pharmacists handling drugs and medical devices must comply with requirements of ZFDCA, 2006 and its associated Regulations.

3.0. COMPLIANCE ACTIVITIES

3.1. Education, Consultation, and Information

Compliance is facilitated when legislative and regulatory requirements are clearly identified and understood, and accessible to all stakeholders. ZFDB encourages industry and other stakeholders to participate in the development of all quality and safety standards and regularly consults with industry on legislative, regulatory, and policy issue, and proposed amendments thereto.

The Board promotes compliance through educational activities and the sharing of information on regulatory matters. The Board also provides information to consumers to enable them to be active participants in maintaining their health and the safe use of marketed products.

3.2. Compliance Monitoring

ZFDB conducts monitoring activities to assess the compliance of regulated parties with the Act and its associated regulations, in accordance with established policies and procedures. These proactive activities include a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product sampling program.

3.3. Compliance Verifications and Investigations

Where the Board identifies or is notified of a potential non- compliance, it takes steps to determine whether non-compliance has occurred. Potential non- compliance may be identified by consumers complaints, industry complaints, referrals from regional authorities and other regulatory agencies, international partners or the Board's compliance monitoring activities.

3.4. Responses to Non-compliance

Where non-compliance is brought to the attention of a regulated party, it is the regulated party's responsibility to take timely and appropriate action to comply with legislative and regulatory requirements. Compliance is normally achieved through a cooperative approach among the regulated party, and the Board. However, a number of enforcement options are available if necessary, particularly when the regulated party is unable or unwilling to correct non-compliance. The Board's role is to ensure that the regulatory party complies with the regulatory decisions so that the ultimate consumer of any regulated products has access to safe and quality products.

The primary objective of the response strategy is to manage the risk to Zanzibarians and use the most appropriate level of intervention to ensure that the responsible regulated party brings the product or activity into compliance. To this end, the Board evaluates instances of non-compliance to determine the most appropriate action(s) to be taken. Such actions may be undertaken independently, concurrently or sequentially with other actions, if the circumstances warrant it. This determination considers the various circumstances of each case and takes into account, along with other applicable information, the following or any combination of the following factors:

- The risk to health and safety, including the absence of a valid marketing Authorization;
- Compliance history of the regulated party;
- Whether the regulated party acted with indifference or premeditation;
- The degree of cooperation offered by the regulated party to ZFDB;
- The likelihood that the same problem will reoccur;
- The likelihood of the enforcement action being effective;
- The need to maintain public confidence in the programs administered by ZFDB; and
- ZFDB priorities and available resources.

3.5. Compliance Measure Initiated by the Regulated Party

A number of compliance measures may be considered when it is felt that the risks associated with the non-compliance may be appropriately managed without recourse to regulatory measures. One or a combination of the following measure may be considered.

3.5.1. Consent to Forfeit

Consent to forfeit is an agreement between ZEDB and the regulated party for the regulated party to surrender control of a product to the government. This shall be done as stipulated under section 100 of the Act.

When inspector is satisfied that such product is unfit for intended use he may affix any mark or other designation and where necessary dispose of at the owners cost or destroy in a manner he may deem appropriate.

3.5.2. Recall

A recall is a method for removing a distributed regulated product, including its labeling, that

violets the Act and/or its associated Regulations, or that may present a risk to the health of consumer. Recalls of regulated products may be undertaken anytime, in response to a formal request by the Board or on the initiative of regulatory party to carry out the combined responsibility to ensure compliance with the legislation, and to protect the health of consumers. A firm's recall does not preclude other actions which could be taken by the Board or the firm.

With respect to a regulated product, "recall" means a firm's removal from further sale and use, of a distributed product that presents a risk to the health of consumers or violates legislation administered by ZFDB. Every person running a business of a product regulated by the Act must maintain such a recall mechanism to enable the removal of a distributed risk product.

3.5.3. Voluntary Detention

A voluntary detention is an agreement between ZEDB and the regulated party to maintain control of a particular product. While the ZFDCA, 2006 under section 100 provides authority for product seizure or detention, a voluntary detention under the custody of the regulated party may be appropriate if the Board is confident that such person carrying on the business will comply with the conditions of the agreement. ZFDB will monitor the effectiveness of a detention and may take other enforcement action, e.g. seizure as appropriate.

3.5.4. Voluntary Disposal

A voluntary disposal is an action by a regulated party to prevent further distribution of a non-compliant product, by actions such as disposal, destruction, or returning it to the manufacturer.

In considering whether voluntary disposal is appropriate compliance action, the Board will consider the following factors:

i. The degree of cooperation offered by a regulated party on prior occasions.
ii. That the product will be rendered non-saleable/usable.

3.5.5 Voluntary Stop Sale

A voluntary consent by the distributor to stop the sale and distribution of a product at any level in the distribution chain.

4.0. REGULATORY MEASURES

A number of regulatory measures are available to ZFDB in order to achieve compliance by regulated parties. These are generally exercised under the powers of the Act and its regulated Regulations and other relevant legislation. The following measures can be considered.

4.1. Customs Activities/Target

In order to determine whether a product should be refused or permitted entry into Zanzibar, the ZFDB may request the Tanzania Revenue Authority (TRA) and Zanzibar Revenue Board (ZRB) to target a specific commodity or importer that has been identified a having potential for non-compliance with the Act and its associated Regulations. The Board may order that a specific product be refused entry and serve such copy of an order to TRA and ZRB that a product be refused entry into Zanzibar on the basis of non-compliance with legislative or regulatory requirements. The Board may order the return to the country of origin of such product or use such other appropriate alternatives to ensure that compliance is done without risk involved.

4.2. Forfeiture Following Seizure or Prosecution

Forfeiture is an action taken after a seizure or a conviction (see “prosecution”), whereby control of the product is surrendered to the government.

4.3. Injunction

The Board may seek for an injunction order to remedy any risk arising from product which contravenes the provision of the Act.

An injunction is a court order that intends to maintain a status of an existing circumstance. Injunction action will be considered when a violation constitutes a significant and immediate threat or when a regulated party is non-compliant with a court order.

4.4. Prosecution

A prosecution is a legal proceeding in which a court of criminal jurisdiction determines whether there has been a contravention of the applicable statute or regulation and if so, the appropriate penalty. The Board considers recommending that charges be laid if the non-compliance of a product or activity can be linked to any of the following criteria:

i. It creates a health risk;
ii. Is habitual offender;
iii. Was premeditated, indifferent, reckless or a marked departure from a reasonable standard of care; or
iv. Other enforcement activities have proven unsuccessful or suggest that the contraventions will likely appear to continue.

4.5. Public Warning/ Public Advisory

When there is an imminent health hazard associated with a product or group of products present in the marketplace, the UIE may recommend to ZFB management that ZFDB informs the population at risk by means of a public warning or public advisory. A public advisory will generally be accompanied by a letter to industry, food and healthcare professionals via their associations to inform them of potential health hazards.

4.6. Refusal, Suspension or Amendment of Establishment License

ZFDB may refuse, suspend or amend an establishment license under the authority provided in the Act under certain circumstances. Such circumstances are where there are reasonable grounds to believe.

i. That any provisions of the Act and its associated Regulations have been contravened;
ii. That the license has made a false or misleading statement in its application for an establishment license, or in the case of medical devices that the failure to suspend an establishment license would constitute a risk to the health or safety of patients, users or other persons; and
iii. If it is necessary to do so to prevent injury to the health or safety of the consumers, patients, users or other persons.

The Board may include or amend terms and conditions of a food establishment license, drugs license or a medical devices establishment license if it is believed on reasonable grounds that it is necessary to do so to ensure compliance.

4.7. Regulatory Stop Sale

For regulated products with a marketing authorization, ZFDB may require in accordance with applicable regulatory provisions, that a regulated party provide evidence to address quality and safety concerns and refrain from selling the product until those concerns have been addressed.

In the case of product without authorization the sale will cease until compliance is met.

4.8. Seizure and Detention

An administrative seizure and detention is an enforcement tool for immediately controlling non-compliance. ZFDB may take control of non-compliant articles (e.g. drugs or medical devices) under the administrative seizure and detention see section authority provided in subsections 100(1) and 107(d) (e) of the Act. When determining whether to implement an administrative seizure and detention, the Board will consider the risk to health and safety and the compliance history of the regulated party.

Evidentiary seizures are used to gather evidence for a prosecution. The Board may seize non-compliant articles as evidence under the authority of a search warrant obtained pursuant to section 110 of the Criminal Procedure Act, 1985, in collaboration with other law enforcing organs.

4.9. Suspension or Cancellation of Marketing Authorization/Product License

When a regulated party is not in compliance with legislative or regulatory requirements a significant health risk exists and there is no indication that the regulated party will comply, ZFDB may suspend or cancel the marketing authorization (e.g. suspension or cancellation of product manufacturing license).

4.10. Warning Letter

The Board may issue a warning letter to a regulated party when it is believed that non-compliance has occurred or is continuing and the risk to human health or safety does not warrant an immediate and stronger enforcement action. The Board will consider the compliance history of the regulated party any efforts to achieve compliance. Where a warning is ignored or disregarded, or is a third warning letter the Board may escalate its enforcement activities.

5.0. INSPECTIONS

Inspections of regulated products shall be carried out by inspections in the appropriate manner as provided for in the Act. The inspectors shall take immediate action to control and manage any risks which may arise from contravention of the Act pending any further action as may be

found just by the Board.

In exercising their powers for ensuring compliance with the Act and for proper administration of inspections; inspectors shall take immediate actions on the following scenarios which contravene the Act or Regulations or rules made therein:

S/N	VIOLATIONS	Enforcement measures
1.	Regulated products in the market containing or consisting of any poison or any other thing which constitute or contain evidence of breach of any provision of the Act	• Seizure and detention of those products as per section 107(1) d, e of the Act and issue a warning letter.
2.	Imported product regulated under the Act contravenes any provisions of the Act	• Detain and order disposal or return of such product(s) to the country of origin as per section 107(1) g.
3.	Pharmacy operating without pharmacist (superintendent)	• Issue a 90 days closure notice to the owner to dispose of stock or secure services of a pharmacist as per section 48 and 49 of the Act.
4.	Operating a product manufacturing facility without key technical personnel, quality control laboratory and any other critical deficiency of the Act.	• Issues a stop order of production till the facility secures the service of the key personnel, provides quality control laboratory facilities or rectifies the critical deficiencies noted.
5.	Premise operating business regulated under the Act, without registration certificate or license contrary to section 19 and 20 of the Act.	• Closure of the premise
6.	Registered and licensed premise by the Board found with un-renewed/expire license	• Order stop of operation until renewal of license within specified time frame
7.	Found in possession of counterfeit product	• Seize the products and institute criminal proceedings in a competent court

S/N	VIOLATIONS	Enforcement measures
8.	Illegally imported products or found in possession of unregistered products or sale of unauthorized products in a registered premise.	• Seize the product and issue a warning letter
9.	Sale of expired products	• Order stop sell and product destruction and issues a warning letter
10.	Registered premises not conforming to the requirement of that business e.g. regulated products stored under improper conditions	• Order remedial actions within a specified time frame
11.	Dispensing prescription and controlled products without prescription	• Remedial order be implemented within a specified time frame
12.	Lack of improper documentation and no record-keeping	• Remedial order be implemented within a specified period of time

Notwithstanding measures instituted by the Board or inspectors the authority shall be at liberty to institute any criminal proceeding before a competent court of Law.

5.1. Appeals

ZFDB recognizes that some of its decisions may be disputed by regulated parties. In the interest of transparency and fairness, the Board has implemented internal appeal processes to facilitate the resolution of contentious issues that arise in making some of its decisions (e.g. drug establishment licensing). The Board will however, ensure that such internal appeals do not compromise its compliance and enforcement activities.

EFFECTIVE DATE

This first version of ZFDB's ***Compliance and Enforcement Policy*** is effective as of May 2013.

Dr. Burhani O. Simai
REGISTER