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The Regulation Of Food And Medicine Under The Ethiopian Legal Regime; In Light Of International Legal Frameworks

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Declaration

Firehiwot Mequanint, hereby declare that this research publishable manuscript paper is original and has never been presented in any other institution. To the best of my knowledge and belief, I also declare that any information used has been duly acknowledged.

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This thesis manuscript has been submitted for examination with my approval.

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Contents

Abstract

The Ethiopian government is undertaking multiple initiatives to protect the health rights of its citizens and to meet obligations set by international laws but the pattern of the pattern of the regulation and the institutional arrangement have not been properly investigated. This article analyses the Ethiopian legal and institutional frameworks designed for the regulation of food and medicine. Accordingly, the article argues that some laws governing food and medicine are not sufficient and modern and the existing laws have left loopholes in mandate overlapping between government institutions in the regulation. This article further argues that the unappealing nature of the food and medicine regulatory regime is attributed to several factors, including the lack of specialized separate government organs regulating food and medicine separately, the absence of consistent institutional arrangements, the existence of wide illegal trade on food and medicine and other factors relating to the public awareness towards illegal practice on food and medicine.

Key words: Food; Medicine; EFDA; Pre Market Regulation; Post Market Regulation

Introduction

The Ethiopian government has made significant strides in safeguarding public health by implementing various initiatives aligned with international legal frameworks. However, a comprehensive examination of the regulatory landscape for food and medicine reveals gaps, inconsistencies, and institutional challenges that hinder effectively protecting citizens' health rights. Accordingly, this article aimed to delve into the Ethiopian legal and institutional frameworks governing food and medicine regulation, identifying both their strengths and shortcomings. By examining the Ethiopian regulatory regime in the context of international legal frameworks, this study aims to identify areas where improvements are needed. It will explore the potential for strengthening existing laws, establishing more specialized and efficient regulatory bodies, and addressing the challenges posed by illegal trade and public awareness. Ultimately, the goal is to contribute to a more robust and effective regulatory system that protects the health and well-being of Ethiopian citizens.

Methodology

As the study examines the law and the practices on the regulation of food and medicine, it has employed both doctrinal and non-doctrinal research methodology. The doctrinal research methodology is used to analyze the laws and official documents, while the non-doctrinal (empirical) research methodology is used to assess the practices.

Research Approach and Design

The study used a qualitative research approach to assess the perception and opinion of the relevant stakeholders from EFDA. Also, the study adopted descriptive and analytical research designs to describe the practical regulation of food and medicine and make a critical analysis of different materials.

Sample and Sampling Technique

The non-probability purposive sampling technique is used to collect data from purposefully selected key informants EFDA. Two key informants from food administration and two informants from medicine regulation were randomly selected. Accordingly, one informant from the food inspection and law enforcement team, one informant from the food registration and permit work team, one key informant from the medicine manufacturing inspection and law enforcing team, and one interviewee from the medicine registration and market permit team. A total of four key informants were enlisted for the study. Data Sources and Methods of Data Collection Both primary and secondary data sources were used to collect data. A semi-structured interview is used to gather primary data from the key informants from EFDA. Since EFDA is the primary institution involved in food and medicine administration its selection is likely to generate meaningful data for the study. In addition to the interview, primary documentary sources such as the Codex Alimentarius standards, The WTO, Agreement on technical barriers to trade and GATT, and domestically the FDRE Constitution, The Proclamation defining Powers & Duties of the Executive Organs of Ethiopia, the Food and Medicine Administration Proclamation and the Food, Medicine and Health Care Administration directive other laws and, regulations of the federal government as well as official documents and materials were also analyzed. Furthermore, the study also employed the relevant literature, books, journals, and articles as secondary sources.

Method of Data Analysis

The data collected from primary and secondary sources were organized and presented in subsections based on their similarities and relations. As the study employed a qualitative research approach, the thematic analysis method was used to analyze and interpret the data. A qualitative analysis of relevant theoretical concepts, international and national rules on food and medicine, and other collected data is conducted. The data collected from the key informants through interviews, personal observation, and other documents were analyzed qualitatively based on a descriptive analysis method. Moreover, a comparison of the food and medicine laws of Ethiopia with international legal frameworks on food and medicine was also made to make the findings more reliable and complete.

Organization of the Paper

The paper is organized into three sections. Section one provides the conceptual frameworks, including food and medicine, the need for food and medicine regulation, the enforcement of food and drug protections, and legal frameworks on food and medicine in the international arena. Section two tries to critically examine the Ethiopian laws on food and medicine Section three then describes empirical data, highlights the regulation of food and medicine practices, and presents the descriptive findings.

I. The Concept of Food Safety and Medicine

Though various efforts are being exerted to define the term food safety, it has no universal definition for its regulation through legislation.[1] However, the conceptual understanding of food safety from the perspective of food science is defined as 'issues surrounding the production, handling, storage and cooking of food that determines whether or not it is safe to it.'[2]

Medicine is another concept dealt by the paper and it's defined as, a substance that is used in treating disease or relieving pain and that is usually in the form of a pill or a liquid.[3] Medicine has a favorable effect on our health. As explained above, medicine can be taken as a type of

[1] Eat Safe: Evidence and Action towards Safe, Nutritious Food, 'Review of Food Safety Policy and Legislation in Ethiopia' January 2022

[2] David A. Bender, *Dictionary of food science and nutrition*, (Oxford University press 4th edition 2009) 102

[3] Hasanthi, Drug V.s Medicine, available at <https://pediaa.com/difference-between-drug-and-medicine/>

drug. Medicine is sometimes used interchangeably with drugs, but it does not have the negative connotations associated with drugs.[4]

A. The Need for Food and Medicine Regulation

The need for regulation of food and medicine answers the popular question, why are food and medicine subjected to regulation? Accordingly, the following are justifying factors of food and medicine regulation.

The need to safeguard public health is usually based on protecting their citizens from unnecessary risks and ensuring the socio-economic development of their country. Safeguarding of public health by tackling risks emanating from food and medicine conducted by preventing unfounded risks, to which the society would be exposed, and by enhancing markets for economic development.[5] The absence of institutional and legal frameworks regulating food and medicine paves a wide loophole in maintaining public health since it opens room for providing risky food and medicine on the markets for the public at large.

The Maintenance of Quality Control is another pushing factor for the regulation of food and medicine. The regulation of food and medicine ensures the products released for use in their jurisdiction are properly evaluated and meet appropriate standards of quality, safety, and efficacy that are maintained throughout all stages of the product lifecycle and supply chain, including manufacturing, production, packaging, and distribution.[6]

The Rapid Growth of Trade has also left its footprint for the regulation of food and medicine. Trade conducted at international and domestic levels allows the rapid transfer of risks emanating from different sources due to the movement of food and medicine from one place to another.[7] The presence of elongated time between food processing and consumption leads to additional opportunities for contamination, time, or temperature abuse, increasing the risk of foodborne

[4] ibid
[5] Melese Temesgen, 'Food Standards, Food Law and Regulation System in Ethiopia: A Review' (2015) 5 Public Policy and Administration Research 57
[6] Alastair J. Wood and Patricia Cuff, *Regulating Medicines in a Globalized World: The Need for Increased Reliance among Regulators* (National Academies of Sciences, Engineering, and Medicine 2020) 3

[7] Caroline Smith DeWaal and Nadine Robert, Global and Local: Food Safety Around the World 2005 The Center for Science in the Public Interest 5

illness. Increasing trade also means that new and unfamiliar foodborne hazards can more easily reach consumers who have not developed immunity to those pathogens.[8]

The Prevention of Fraud is also another dictating factor for food and medicine regulation. Most states around the world promote public health by preventing fraudulent activity with food, drugs, and an array of other public health products that enter interstate or domestic commerce through enactments or rules.[9] Indeed, the primary purpose of the rules is to safeguard and protect consumers from exposure to dangerous products affecting public health and safety. The food and medicine regulations are the main tools regulating the safety of most foods, food additives, color additives, dietary supplements, prescription and non-prescription drugs, medical devices, cosmetics, and tobacco products by prohibiting acts like adulteration and misbranding.[10]

B. The Enforcement of Food and Drug Protection

The enactment of rules means nothing unless they are implemented. It must be put into effect or implemented by an agency of the executive branch. Just like any other rules, the food and drug laws should be enforceable for them to be effective. The enforcement of food and drug regulation is designed to address issues about institutions tasked with addressing the food and drug regulations, whose general mission is to promote and protect public health by ensuring the safety, efficacy, and truthful labeling of the products it regulates.[11] Accordingly, the enforcement of food and drug protection involves the following actions at the time of breach of the rules on food and drug protection.

The civil enforcement is the primary action that can be taken by the food and medicine enforcing institution can be civil or criminal against the violators of the regulations. As part of the civil enforcement action, the institution has several administrative tools for enforcing the rules; hence the civil enforcement actions that can be taken by the enforcing organs include the issuance of warnings and letters, import alerts, recalls, and civil money penalties.

[8] ibid
[9] Kathryn B. Armstrong and Jennifer A. Staman, 'Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues' 2014 7 Congressional Research Service 1
[10] ibid
[11] ibid 4

The criminal enforcement is another action involved in food and medicine protection which includes the taking of the following actions, fines and imprisonment, for violating certain provisions of the laws.

C. The international Frameworks Regulating Food and Medicine Internationally

Codex Alimentarius is a compilation of harmonized international food standards, guidelines, and codes of practice collectively, these Codex texts aim to protect consumer health and promote fair practices in the food trade and are developed with the joint input of independent experts and by public participation.[12] Due to the advisory nature of the standards, guidelines, and codes of practice of codex, to become legally enforceable, countries must voluntarily translate them into national legislation or regulations.[13] The codex has specified different benchmarks for standardized food law by providing food law components. However, many components of food law are now considered fundamental to the objective of providing consumer protection and they are usually found in all modern food law.

General Agreement on Tariffs and Trade (GATT) is another international framework on food and drugs. For the maintenance of fair competition in the international markets, General Most-Favoured-Nation Treatment and National Treatment on Internal Taxation and Regulation principles are the basic principles of WTO which advocates non-discrimination in trade.[14]

Technical Barriers to Trade Agreement (TBT), Issues pertaining to standards and certification in general are matters uncovered by the Agreement on Technical Barriers to Trade. Under TBT there are two recognized standards, accordingly the technical regulation is the first one under which compliance is mandatory and the second being a standard which is not mandatory.[15]

[12] WTO and FAO, *trade and food standards* (2017) 3

[13] ibid

[14] FAO, Overview of standards: international agreements, national regulations and private standards 4, available at: <https://www.fao.org/3/a1245e/a1245e02.pdf>

[15] ibid

Technical regulations are prohibited from becoming trade restrictive unless it is aimed at fulfilling a legitimate objective as per the TB.[16]

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) is another rule dealing with food and drugs in the international arena. As per the agreement of SPS, states are allowed to set their standards which are based on science on products entering their territory.[17] However, the measures taken should be applied only to the extent necessary to protect human, animal, or plant life or health and don't have to in arbitrarily or unjustifiably manner to discriminate between countries where identical or similar conditions prevail.[18]

D. The legal frameworks on food and medicine in Ethiopia

Legal frameworks are crucial for promoting, developing, and regulating the health sector. They don't just set the rules but also encourage growth by attracting investment and participation from various parties' private sector and stakeholders in the healthcare system. The health sector has a direct relation with food and drugs since the health sector deals with the life of a human being; it's all about the protection of the health of citizens; hence, strict and effective regulation is very important. The FDRE constitution provides a baseline framework for the state structure, rights, and duties of citizens and government with the health rights of the public at large. The 1995 FDRE Constitution also provides a general framework for public health and the right to a clean and healthy environment. The constitution, under Article 41(4), imposes an obligation on the state to allocate ever-increasing resources to provide public health, education, and other social services.[19] The constitution furthermore has enshrined citizen's right to a clean and healthy environment under article 44.

The Food and Medicine Administration Proclamation is another domestic legislation promulgated for the regulation of food and medicine. Though the existence of different

[16] Agreement on The Technical Barriers to Trade (Here in after TBT, 1995)
[17] FAO (n 14)
[18] ibid
[19] The Constitution of the Federal Democratic Republic of Ethiopia Proclamation No.1/1995, FEDERAL NEGARIT GAZETA art 41(4) [hereinafter FDRE Constitution].

legislations on the area of food and medicine is unquestionable, the primary legal framework regulating food and medicine is the Food and Medicine Proclamation.[20]

E. The institutional frameworks on food and medicine in Ethiopia

In Ethiopia executive organs of the federal government of EFDA and delegated regional bureaus are designed institutions to maintain public health by tackling challenges emanating from food and medicine. Among the governing bodies of the country, ministries, institutes, and agencies through which Ethiopia distributes executive powers, three ministries have the legal mandate to implement Ethiopian food and nutrition policy: the Ministry of Health, Ministry of Agriculture, and the Ministry of Trade and Regional Integration.[21]

i. The examination of the food and medicine regulation in Ethiopia

The regulation of food and medicine in Ethiopia is facing the following challenges sourced from various roots.

a. Challenges Pertaining to definition

The Ethiopian Food and Medicine Administration Proclamation which is the regulatory legal framework on food and medicine while defining food, has considered food as any substance, whether processed or semi-processed, which is intended for human consumption.[22] The proclamation's failure to include foods other than processed and semi-processed food as food has limited the scope of the authority of the EFDA only on regulating processed and semi processed foods, hence foods other than processed and semi processed are regulated by the Ministry of Agriculture and Ministry of trade and regional integration which is opening rooms for mandate overlapping between those institutions while regulating imported and locally produced products.

As per the interviews conducted with Mulatu, he has explicitly confirmed that had the term food has been defined in a broader manner the food and medicine regulation regime would be different and might solve mandate overlapping in regulation being reflected with the ministry of

[20] FDRE the Food and Medicine Administration Proclamation No.1112/2019 (Here in after called The food and medicine proclamation)

[21] Global Alliance for Improved Nutrition, 'Consumer and Vendor Perspectives on and Practices Related to Food Safety in Ethiopia: A Review. A USAID Eat Safe Project Report' (2022) 8

[22] Food and medicine administration proclamation article 2 (1)

agriculture and Trade and regional integration and the regulatory authority of EFDA might extend towards agricultural and other foods sold on informal markets.[23]

b. The lack of Sufficient Legal Frameworks

Enactment of regulations and guidelines surrounding food production and distribution can have a significant negative impact on public health. However, as per the current EFDA practice, the proclamation on food and medicine administration is not backed by regulation, and still, regulation is not promulgated though it plays a key role in maintaining targeted aims by the proclamation. Moreover, Mr. Mulatu has asserted that EFDA doesn't have regulations, guidelines, and manuals regulating food additives and supplements though there is a risk of contaminated or adulterated food entering the market, leading to foodborne illnesses and outbreaks.[24] Despite the changing and dynamic nature of the medicine trade, in Ethiopia, the medicine policy being applied is the one that was enacted in 1993 which is old and outdated.[25]

c. Organizational Structure Related Challenges

Under the Ethiopian governmental institutions organization regime, the regulation of both food and medicine is granted to EFDA.[26] Such a grant of amalgamated power for EFDA for regulating food and medicine is not wise since the organ is administering both matters involving food and medicine due to the absence of a designated executive organ that handles food and medicine separately.[27] Furthermore, Mengistu in an interview urged for the formalization of separate government organs which are dedicated only to the regulation of food and also specialized designated organs entertaining matters related to medicine.[28]

d. Inconsistent Institutional Arrangements

One of the institutions that play an important role in protecting public health in the health sector was the Ethiopian Food, Medicines, Health Care Administration and Control Authority

[23] Interview with Mulatu Tesfaye, EFDA food inspection and law enforcing team leader Addis Ababa, Ethiopia, April 13, 2024 (here in after interview with Mulatu)
[24] Interview with Mulatu
[25] Interview with Getachew Genete, EFDA medicine manufacturing inspection and law enforcing team leader Addis Ababa, Ethiopia, April 15, 2024 (here in after interview with Getachew)
[26] The repealed Food and medicine administration proclamation 1112/2019 Article 2 (57)
[27] Interview with Mulatu
[28] Interview with Mengistu Tesfaye, EFDA food registration and permit work team executor, Addis Ababa, Ethiopia, April 14, 2024 (here in after interview with Mengistu)

(EFMHACA, since its establishment by Proclamation.[29] However due to different reasons, the competent office of the FDRE, the Food and Drug Administration of Ethiopia, has been re-established as the Food and Drug Control Proclamation 1112/2019 article 2 (57), and the authority and responsibility given to the authority, the EFDA is to control food safety, drug and medical device safety and quality, and tobacco products to prevent harm to public health.[30] The absence of consistent institutional arrangement in handling public health by regulating food and medicine is creating different challenges since each institutional establishment and dismantling results in granting and taking away of powers on food and medicine administration.[31]

e. Overlapping of Mandates

The regulation of food and medicine involves, EFDA, the Ministry of Agriculture, and the Ministry of Trade and Regional Integration, though they have different roles in the regulation of food in the country. According to conducted interviews with EFDA officials in general and interviews with Mulatu, mandate overlapping between the three government institutions is still being reflected and the situation is not solved until today despite raising the issue in the concerned area.[32] A good insight in this regard raised by Mengistu is the regulatory power concerning imported food which is practically being regulated by EFDA, the Ministry of Agriculture, and the Ministry of Trade and Regional Integration simultaneously.[33] In addition to the above-mentioned challenges widening of illegal trade, the awareness of the public, and the lack of performance indicators measurement tools are posing another obstacle in the food and medicine administration.

II. Conclusion

Based on the qualitative analysis of the existing legal and institutional framework buttressed by its practical state in Ethiopia, it can be concluded that the assessment of the state of food and medicine regulation in Ethiopia is characterized by bottlenecks in the existing legal and

[29] The repealed proclamation of Definition of Powers and Duties of the Executive Organs of the Federal Democratic Republic of Ethiopia Proclamation No. 1097/2018 article 33 (18) (E)
[30] Definition of Powers and Duties of the Executive Organs Proclamation No. 1263/2021 article 66
[31] Interview with Mengistu Legese, EFDA medicine registration and market permit team leader, Addis Ababa, Ethiopia, April 16, 2024 (here in after interview with Mengistu)
[32] Interview with Mulatu
[33] Interview with Mengistu

institutional frameworks which is reinforced by practical factors that hindered the proper realization of public health by regulating food and medicine.

Ethiopia does have legal and institutional frameworks regulating food and medicine. However, there are internal gaps which are in the already established legal and institutional frameworks and external problems that are practical factors that hinder the effective regulation of food and medicine. Despite the existence of legal frameworks designed for the regulation of food and medicine for protecting public health, compared to internationally enacted standards on food and medicine, some of the food and medicine legislation provisions have failed to adhere to international standards.

Though the Food and Medicine Administration Proclamation has defined products regarded as food for regulatory purposes, it has failed to provide comprehensive definition that grants regulatory power to EFDA for regulating foods other than processed and semi-processed food. Moreover, the existing Ethiopian legal regime governing food is not sufficient and failed to address vital issues related to food and the presence of old and outdated medicine policies in the country has failed to update itself with the changing scheme.

Institutionally, instability of the executive organ endowed with the responsibility to protect public health; absence of clear provisions on the institutional linkage between EFDA, the Ministry of Agriculture, and the Ministry of Trade and Regional Integration about their role and responsibility in regulating food and medicine; the absence of specialized dedicated governmental organ regulating food and medicine separately; overlapping of mandate between EFDA, the Ministry of Agriculture, and the Ministry of Trade and Regional Integration in regulating the matters is being reflected.

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