Regulating the Food and Drug Sector in Ethiopia: Current Status and Concerns

Binnyam Ahmed, St. Mary's University

Abstract

Of the various functions attributed to law, one is the traditional functions of the regulation of societal behavior. Law is characterized by the feature of normativity for its capacity to establish a norm in society. Business law, specifically economic/social regulation in law is one of the manifestations of this norm-building process. The time which favors for a government and its enforcement organs distanced from the market as much as possible is being replaced by a more regulation-friendly market system. Certain areas of business call for regulations for stronger reasons. The food and drug industry comes at the forefront of this sector. This article presents the constitutional and legal basis of the food and drug industry regulation in Ethiopia. It starts by presenting the traditional arguments for regulation, in general, and the food /medicine sector, in particular. A global approach to the food and drug industry is presented to lay the foundations for Ethiopian case narration. This is followed by the investigation of the FDRE Constitution for locating a basis for regulation of the industries. An exhaustive examination of the current laws which have a direct relation with regulating the food and drug industry is presented paving the road for the discussion of the major issues worthy of consideration in the discourse of regulation of the food and drug industry in Ethiopia. The article argues that the Ethiopian regulatory legal framework is constitutional and there indeed is a sufficient basis for the food and drug regulation, yet the fear of capture of the regulator by the industry is not sufficiently addressed in the legal framework.

Keywords: Regulation, Food and Medicine Regulation, Legal Basis, Constitutional Basis

Acronyms:

FMAP- Food and Medicine Administration Proclamation

PHP- Public Health Proclamation

TCCPP- Trade Competition and Consumer Protection Proclamation

ADPCP- Animal Disease Prevention and Control Proclamation

LAMP- Live Animal Marketing Proclamation

Brief Overview of Regulation in the Food and Drug Industry

A study conducted to assess the understanding of the term regulation, as used in different disciplines, has concluded a common understanding should end in considering it as the intentional intervention in the activities of a target population.[1]

Andrei Shelifer's work sums up the prominent theories around regulation in an effort to understand the justification and prevalent views around the concept.[2] He presents the public interest theory of regulation, the contract theory of regulation, and the capture theory with some other alternative ideals on the concept to find commonalities among the various theories.[3]

Based on the assumption that unhindered markets often fail because of the problems of monopoly or externalities, and governments are benign and capable of correcting these market failures through regulation of the public interest theory advocates for government interference in the market.[4] Arguing the working of competition and private ordering in place of regulation, others have called for courts in enforcing private contracts and acting as powers to remedy market failures.[5]

A skeptical view of the regulation scenario is best described by the theory of capture as it predicts the fear that the process of regulation will be captured by the industry and various interest groups.[6] Though not formulated in the exact capture term, the renowned economist, Joseph Stigler has argued regulation as one product in the market system that does not arise to advance the overall public interest by correcting market failures but is acquired by the industry and is designed and operated primarily for the benefit of the industry.[7]

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[1] Koop Christel and Lodge Martin, what is regulation? An interdisciplinary concept analysis. Regulation and Governance (2015) P 23.

[2] Andrie Shilfer (2005) *Understanding Regulation, European Financial Management*, 11, 4; pp. 439–451.

[3] Ibid

[4] Id p 440

[5] Avery Katz (1996) *Taking Private Ordering Seriously*, University of Pennsylvania Law Review, 144; PP 1755-1758. A detailed account of Coase theorem in establishing private ordering and empowering the court to remedy transaction cost by opting for private parties and courts or as the author use another person's expression and refer them as transaction cost engineers is presented in this article.

[6] An excellent manifestation of this capture theory is the case study on Nigerian pharmaceutical regulatory agency. As to the authors finding regulation of the pharmaceutical sector touches the cords of divergent powerful interests in business and can, therefore, be acrimonious. See Olugbenga, Ebenezer Olatunji (2013) *The Politics of Pharmaceutical Regulation in Nigeria: Policy Options for Third World Countries*, Public Policy and Administration Research, 3,8; PP 89-100

[7] Christopher Carrigan & Cary Coglianese (2016), *Capturing Regulatory Reality: Stigler's the Theory of Economic Regulation*, University of Pennsylvania Faculty Scholarship. Paper 1650. P 1. For the full article of Joseph Stigler see below note 14

Traditional regulations influenced the structure of industries and limited the range of behaviors observed defining markets and constrained entry.[8] It is claimed that the obvious view of regulation as legal rule backed by penalties for noncompliance is an incomplete understanding of regulation.[9]

Though arguments over the proper justification as well as implication of regulation keep on, one sure fact is that a regulation is increasing in every sector of the economy and providing wider powers to the government and its regulatory agencies to interfere in the operation of the market with the aim of protecting consumers and the public interest.[10]

Regulatory approaches usually take two forms: economic and social regulation.[11] While the primary rationale for economic regulation stems mostly from attempts to control the excesses of laissez-faire economics, particularly the negative effects of monopoly power in terms of price, entry, exit, etc., the economic rationales for many social regulation programmes are the problems of externalities that relate to market failure.[12] Economic regulation consists structural and conduct regulation where in the former is concerned with market structure while the latter regulates behavior within the market.[13] It thus controls profits, sets prices, and determines who can participate in a market or use a particular resource.[14]

Social regulation controls polluting by-products of production, sets health and safety standards for products and workplaces, restricts the content of information provided by sellers through advertising and other means of describing products to consumers, and establishes requirements to protect buyers from fraudulent, discriminatory, or incompetent behavior by sellers.[15]

Yet such a view of considering the social and economic regulation as contrasting policy values is decreasing alarmingly[16] in the advent of new world of regulatory governance which view economic regulation resulting in social objectives and social regulations having economic

[8] Fundamentals of Economic Regulation. Sanford V. Berg (2013) University of Florida.
[9] Peter Drahos and Martin Krygier (2017) Regulation, institutions and networks as it appears in Regulatory Theory, Peter Drahos, ed p1.
[10] OECD (1997) The OECD Report on Regulatory Reform Synthesis, Paris. The article sums up a point in the need for reform on regulations in place yet emphasizes the ever to be present need for regulation of some form.
[11] In a discussion of taxonomy of regulation, a three-tier regulatory form is presented. Economic and social regulation falls in the first tier. The second tier breaks down the economic and social category to a more detail as in market based social regulation or information based social regulation. The third tier contains a more specific grouping as premarket or post market approval. This being said the authors contend on the predominance of economic and social regulation. See Zhoudan Xie & Daniel R. Pérez (2018) A taxonomy of regulatory forms, The GW Regulatory Studies Center, George Washington University.
[12] Reagan, M.D. (1987). Regulation: The Politics of Policy, Boston and Toronto: Little, Brown & Company. P 88.
[13] John Vickers (1997) *Regulation, competition and the structure of price*, Oxford review of economic policy, 13,1; pp 15-26.
[14] For a detailed analysis of various components of economic regulation see Joseph Stigler (1971) The theory of Economic Regulation PP.3-21.
[15]Paul L. Joskow and Roger G. (1994), Economic Regulation as it appears in American Economic Policy in the 1980s, Martin Feldstein, ed. P 367-452.
[16] Clifford Winston and Robert Crandall (1994) Explaining regulatory policy, Brooking's paper; microeconomics P.44 the authors state the view as to how the distinction between institutions which are labelled as social regulators and economic regulators is merging as one necessarily intervenes in the task of the other.

impact.[17] In fact, scholars who studied the cost and benefits of economic and social regulation have shown how the overall benefit of social regulation is providing net benefits to society better than solo economic regulation making the combined understanding of economic and social regulation within the purview of the general concept as regulation essential.[18]

Richard Posner's seminal work on law and economics has explained that the major challenge in social theory is to explain economic regulation.[19] The pattern of government intervention in the market has been a subject of enormous intellectual and political controversy.[20] That was the reason that leads other authors to have an empirically tested justification for economic regulation shifting from a mere value judgment in the discourse of need and benefit of regulation.[21]

It is a historically uncontested fact that from the beginning of civilization, society was highly concerned about food safety and quality; it forced the focus of the government to regulate the issue in a certain manner.[22] Same can be said about drug regulation as authors argue the history of medicine regulation has roots dating as old as 120 BC.[23]

Hence, in connection to food laws/ regulations, the major need to regulate was stated to be protection against harmful products in the enforcement or post-market surveillance context from concerns of adulteration[24]. The safeguards against fraudulent products, those whose labels do not accurately describe what the product contains - known as misbranded- also falls in this category. Prior to an enforcement action, both are considered under a broader umbrella known as the pre-market approval process. The overarching aim remains the same, protecting the consumer.[25]

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[17] Eric Windholz & Graeme A. Hodge (2013) *Conceptualising Social and Economic Regulation: Implications for Modern Regulators and Regulatory Activity*, Jerusalem Papers in Regulation & Governance; p 5.

[18] Robert W. Hahn John A. Hird (1991) *The Costs and Benefits of Regulation*: *Review and Synthesis*, Yale Journal on Regulation, 8(1) p 253.

[19] Richard Posner (1974), *Theories of economic regulation*, The Bell Journal of Economics and Management Science, 5, 2; PP.335-358.

[20] Supra Note 2

[21] John M. Antle (1996) *Efficient Food Safety Regulation in the Food Manufacturing Sector*, American Journal of Agricultural Economics, 78, 5; P.1245

[22] Neal D Fortin (2009), Food regulation, Law science policy and practice, P 3. USA. The author presents registered historical incidents in relation to food safety concerns dating back as early as the fourth century before the birth of Christ showcasing how time immemorial old the issue is.

[23] Lembit Rägo & Budiono Santoso, (2008) Drug Regulation History, present and future, as it appears in Drug Benefits and Risks: International Textbook of Clinical Pharmacology'', revised 2nd edition (C.J. van Boxtel, B. Santoso and I.R. Edwards. IOS Press and Uppsala Monitoring Centre)

[24] Supra note 22, see Art 5 of Reg 299/2003 1/ It shall be prohibited to add or mix any substance to any food so as to increase its bulk or weight, or make it appear better or for any other similar purpose. 2/ It shall be prohibited to partially or completely embed in any food anything harmful to human health or that can affect the safety and quality of the food. Although the term adulteration is usually associated with food it is a concept equally applicable to Drugs. That is the reason why Article 17 this same regulation deals with the issue of medicine adulteration. 1/It shall be prohibited to add or mix any foreign substance to any medicine so as to change its amount, content or weight, or to make it appear better or for any other similar purpose. 2/ It shall be prohibited to partially or completely embed in any medicine anything harmful to human health or that can affect the quality, safety and efficacy of the medicine

[25] Marc C Sanchez, Food law and regulation for non-lawyers, A US perspective, P2. 2ND ed.

The primary mechanism to achieve this goal is to ensure the agencies tasked with enforcing food safety laws can inspect facilities and use enforcement tools to remove harmful or fraudulent products from the market. The enforcement tools also act as a deterrent. Deterrence and inspection together build trust and allow consumers to shop with confidence. The two also protect a brand's reputation.[26]

Generally, the reason for food regulation boils down to the following three reasons:[27]

1. Protecting public health by reducing the risk of food borne illness;
2. Protecting consumers from unsanitary, unwholesome, mislabeled or adulterated food; and
3. Contributing to economic development by maintaining consumer confidence in the food system and ensuring fair practices in the food trade.

A prevalent factor in the medicine sector is the reality that people and governments willingly spend money on drugs because of the role they can play in saving lives, restoring health, preventing diseases and stopping epidemics.[28]

But, in order to do so, drugs must be safe, effective and of good quality, and used appropriately. As the use of ineffective, poor quality, harmful medicines result in therapeutic failure, exacerbation of disease, resistance to medicines and sometimes death, undermining confidence in the health systems, professionals, pharmaceutical manufacturers and distributors the regulation of the development, production, importation, exportation and subsequent distribution of drugs need regulation to ensure they meet prescribed standards.[29]

The basis of drug regulation being drug laws, regulatory tools of standards and guideline nature equip regulatory authorities with the practical means of implementing those laws.[30] In short, drug regulation is the totality of all measures legal, administrative and technical which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information.[31]

The key functions encompassed in the drug regulation include licensing, inspection of manufacturing facilities and distribution channels, product assessment and registration, adverse

[26] Ibid.

[27] FAO/ WHO, Assuring Food Safety and Quality: Guidelines for strengthening National food control system, FAO food and nutrition Paper 76, p. 6.

[28] International Federation of Pharmaceutical Manufacturers & Associations (2017). Since 1928, scientists have discovered and developed 19 classes of antibiotics. Currently, 34 new antibacterial compounds are in development of which 15 are vaccines and 19 small and large molecules 30. With the help of major medical discoveries, the research based pharmaceutical industry has developed more than 35 antiretroviral treatments for HIV/AIDS, essential to control the epidemic. More than 7,000 medicines are in development worldwide, 208 drugs for HIV/AIDS; 1,919 for cancer; 401 for diabetes; and 563 for cardiovascular diseases.

[29] Sauwakon Ratanawijitrasin and Eshetu Wondemagegnehu (2002) Effective Drug Regulation; a multi country study, WHO.

[30] Ibid P.2

[31] Douglas Ball et al (2016) Better Regulation of Medicines Means Stronger Regional Health Security, ADB Brief no.54 P. 2

drug reaction (ADR) monitoring, QC, control of drug promotion and advertising, and control of clinical drug trials.[32]

Global Approach on Food and Drug Regulation

This part of the article presents a brief overview of food and drug regulation at the global level. This will serve as a comparative analysis so as to evaluate the Ethiopian legal framework with regard to existing global trends.

National legal frameworks governing food control and food safety vary widely in their complexity and their coverage reflecting a mix of political, societal, economic and scientific forces playing in that specific country.[33] This seems to be the motivating factor that forced harmonization of the regulatory effort.[34]

The global movement in food and drug regulation is primarily led by joint efforts of international organizations like Food and Agriculture Organization (FAO) of the UN and the World Health Organization. This is not to exclude the different bilateral and multilateral efforts of regulation in the area.[35] This effort will pave the way for the harmonization of regulatory strategy and mechanism enabling a facilitated interaction among countries of the world by avoiding regulatory variation.[36]

The Codex Alimentarius (Food code) has existed for long in different countries. Yet it was the growth of international trade in food that called for an international food standard. As a voluntary international standard, guideline and code of practice, the Codex Alimentarius developed by FAO serve to achieve the regulatory objective of food i.e., safe and quality food with a possibility of being translated to local legislation and regulations.[37] The code generally deals with hygienic practice, labeling, additives, import and export inspection and certification, nutrition and residues of veterinary drugs and pesticides.[38]

[32] Richard A. Merrill (1994) Regulation of drugs and devices: an evolution, Health Affairs, pp. 47-69 in presenting the evolution of drug regulation in the US the authors touch up on the major components of drug regulation.
[33] Supra note 27 p.9
[34] Ileana Dominguez-Urban (1997) *Harmonization in the Regulation of Pharmaceutical Research and Human Rights*: *The Need to Think Globally*, Cornell International Law Journal 30, 2; P 245. For the case of harmonization in Africa see Drug For neglected diseases initiative (DNDi) (2013) The road to regulatory harmonization for Africa, Nairobi
[35] Neil Bolster (1996) *The international legal regulation of drug production, distribution and consumption*, The Comparative and International Law Journal of Southern Africa, 29, 1; pp. 1-15.
[36] Paula Fitzgerald Bone and Karen Russo France (2003) *International Harmonization of Food and Nutrition Regulation*: The Good and the Bad, Journal of Public Policy & Marketing, 22, 1; p 102-110.
[37] http://www.fao.org/fao-who-codexalimentarius/about-codex/en/#c453333 The code has 224 standards, 99 guidelines and 54 codes of practice updated to the year 2019.
[38] Ibid.

In a related discussion, the World Trade Organization's product standard and trade related agreements are the other global governance structure set for food and drugs.[39] The objectives of these agreements among others are basically making sure food is safe for consumers. It ensures such and thereby avoids disguised trade barrier in a name of standards.[40]

The global drug regulation is carried by WHO and the World Trade organization umbrella. WHO has organized the international conference on drug regulatory authorities since the 1980's providing a forum of cooperation and collaboration among regulators from different countries.[41] As most of the drug regulation affects the development of a new drug, the global trade power house WTO has incorporated the issue of drug regulation in the international trade with the Trade Related aspects of Intellectual Property (TRIPS).[42]

Constitutional Basis of Food and Drug Regulation: Ethiopia

The Constitution is the supreme law in Ethiopia.[43] Any law which contravenes the Constitution is of no effect.[44] The provision which states the supremacy of the Constitution also makes it clear that all international agreements ratified by Ethiopia are an integral part of law of the land.[45]

As the primary reason that justifies regulation in the food and drug sector is protection of public health, the constitutional basis can be inferred from appropriate constitutional provisions which mandate the government to set regulatory approach on the sector. The Federal Government in

[39] Here reference is being made to the Agreement on the application of sanitary and phytosanitary measures (SPS) and the agreement on technical barriers to trade (TBT)

[40] For a detailed discussion of how standards in the WTO work in relation to trade in goods and future impact on Ethiopian case please see Binnyam Ahmed(2010) WTO Accession and Required Product Standards: the case of Ethiopia(unpublished LLM thesis)AAU, Faculty of law.

[41] WHO Drug information (2018) 18TH IRCDA Recommendation, 23, 4; pp. 509-518. Accessed from https://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/WHO_DI_32-4_18ICDRA.pdf?ua=1 (June 2021)

[42] As the WTO rules are made with free trade in perspective the concern of developing nations regarding access to patented drugs is the core area of contention in the regulatory framework as controversial as the quality and safety issues. See UNCTAD (2017) Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production PP. 1-57. Roger Kampf (2015) Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation, Staff Working Paper ERSD-2015-07, WTO.

[43] Art 9 of the constitution of the Federal Democratic Republic of Ethiopia.

[44] Ibid. Not only law Art 9 makes customary practice, decision of organ of a state or public official which contravenes the constitution are of no effect.

[45] This can be mentioned as a strong constitutional basis for regulating food and drug in Ethiopia. Most of the standards in place which are meant to govern the sector are copied from global standards. This necessarily calls for the ratification of international standards and agreements by Ethiopia. Article 9(4) by endorsing such ratified standards as laws of the land is paving the way for the constitutionality of any law legislated to govern the sector based on the ratified agreement. A case in point will be the WHO framework convention on tobacco control and PROCLAMATION no 822/2014 which changed the status of the protocol to Ethiopian local law hence resulting in the tobacco regulation legislations which are based on this international convention.

Ethiopia is empowered by the Constitution to establish and implement national standards as well as basic policy criteria for public health.[46]

As the Constitution also empowers the Federal Government to regulate interstate and foreign commerce,[47] it is plausible to argue that any sort of economic regulation in the food and drug sector, as long as it involves interstate and foreign commerce, can fall in the ambit of federal government jurisdiction giving it a valid constitutional basis.

Furthermore, the constitution by providing the power to enact a commercial code[48] as well as inter-state commerce and foreign trade in general to the Federal Government, it allows indirectly the regulation of food and drug market so long as it is in the purview of commercial activity.[49]

It is also possible to argue the right to life constitutional provision being a generic and wider right call for the fulfillment of various side rights to its full realization, one among such being the protection of health of an individual from harmful and dangerous foods or drugs. In such wider approach, any regulatory action on the food and drug sector can be justified to have an aim of achieving full realization of the most valuable constitutionally protected right, thereby providing it a constitutional basis.[50]

In line with this constitutional provision, the policy documents which have a direct relation with food and drug control have designed mechanisms of achieving regulatory impacts. The current national health policy of Ethiopia predates the Constitution in time. Yet mention was made regarding drug control and the need to update public health laws and regulation with development of new rules to help the implementation of overall goal of the policy on health issues.[51]

The recent effort in amending the policy has resulted in a draft health policy which is in circulation for comments and reviews from relevant stake holders. The draft has explicitly made reference to food and drug safety and the need to design a regulatory strategy as part of the health regulation system.[52]

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[46] Art 51(3) of FDRE constitution. Sub Article 20 of this provision also empowers the federal government with powers to establish uniform standards of measurement.
[47] Art 51(12) FDRE constitution.
[48] Art55 (4) FDRE constitution.
[49] Among the long list of activities listed under Article 5of the commercial code of Ethiopia sub articles 1 and 7 can be interpreted to constitute trade in food and drug making the commercial code a law with implication on regulation of same product.
[50] Since years back it is a wide spread news that food items are being banned from the market for failure to fit standards. See this news where more than 50 food items were banned from the market in relation to violation of different standards set by the concerned organ. (see https://newbusinessethiopia.com/health/ethiopia-bans-cooking-oil-children-foods-brands/) Some of the bans directly relate with the health impact they have on Consumers to the risk of death. It is also essential to see how the right to food and water is now provided in the human right discourse to have constitutional bases as are directly attached to right to life. For stronger reason the right to safe food and drug can also be linked with the right to life discourse.
[51] Health Policy of the Transitional Government of Ethiopia (1993) No. 7 No.14
[52] FDRE Draft Health Policy, 2019, No.2.7.2

Accordingly, the legal basis for food and drug regulation can be said to have not only constitutional but also policy level endorsement enabling the legal environment of regulation to effective control.

Finally, it can also be argued that the social objective[53] in the Constitution which states that policies shall aim to provide all Ethiopians access to public health, food and water to the extent the country's resource permit can be understood to provide a basis for food and drug regulation.

If it is the policy objective of the Government to provide food and water to all Ethiopians, it goes without saying that it will be safe food and water. If public health is to be provided safe drugs, it is the core part of the healing process. The provision of safe food and drug will then expand and simply flow the duty laid on the government to provide both in the first place. Due place is provided for the economic power of the Government to fulfil these duties.

Yet when such is possible providing standard and quality must also be ensured. The regulatory action of the Government in the food and drug sector comes whether such is provided by an establishment which runs for profit or by the Government itself as part of fulfilling its constitutional obligation. This can be presented as a constitutional base for food and drug regulation.

Ethiopian Legal Framework on Food and Drug Regulation

The legal basis for food and drug regulation in Ethiopia encompasses the various laws with direct and indirect regulatory impact on the sectors. This section of the article tries to describe and explain major laws of such a nature.

The civil code of Ethiopia has contractual and extra contractual provisions which can be interpreted in favor of regulatory approach. Apart from the contractual approach,[54] whereby parties in a transaction can invoke terms of specific contract to benefit from either warranties or remedies for breach, the extra contractual liability makes a person who manufactures goods and sells them to the public for profit liable for damage resulting from the normal use of the thing.[55]

Understood from food and drug industry any establishment which puts food and drug to the market is by law liable for any kind of health-related damage if such is caused from the ordinary use of the food or drug which allows us to contemplate a defect in relation to the goods supplied.

The Criminal Code of the country makes explicit reference for acts which are committed against public health.[56] Article 525 of the code makes the production, making, trafficking or using

[53] Article 90(1) of FDRE constitution

[54] The arising of regulation was justified as a result of subversion of justice or the failure of contract law to protect functioning of market to perform effectively. See M Korotana (2017) The Emergence of Regulation: Market Failure, Subversion of Justice and Inadequacy of Private Law.

[55] Art 2085 of civil code of Ethiopia.

[56] The Criminal code of FDRE proclamation no. 414/2004 Book IV crimes against the public interest or the community, Title VIII Crimes against public health

poisonous or narcotic[57] and psychotropic[58] substances without a special authorization punishable offence. In connection to foods, Article 527 of the code makes the manufacture, adulteration and sale of injurious or damaged food stuff in such a way endangering public health a criminal act.[59]

The concern for public health is widely narrated in the public health proclamation (PHP).[60] The public health part of the law which deals with different manifestations of the health concern provided a coverage regarding food quality control[61], food standard[62] and water quality.[63] Although the law is silent on drug, these three consecutive provisions are starting points for food regulation. The major concepts in food regulation such as food standard, labeling, permits and registration, and quality verification are incorporated in the law. The sub constitutional norms governing the regulation of the food industry in the Ethiopian context starts from this legislation.

The Trade Competition and Consumer Protection Proclamation (TCCPP) is another legal framework worth mentioning in connection to food and drug regulation. Although criticized for its lack of practical application[64] the law states, in its preamble, the need to prevent the proliferation of goods and services that endanger the health and wellbeing of consumers and the need to ensure the safeness and suitableness to human health as one of the reasons for having the law.[65]

Among the various lists of acts that are considered prohibited is making available for sale goods [66] which are dangerous to human health and safety, the source of which is not known, or which are substandard, poisoned, expired or adulterated.[67] To ensure this, a trader has the duty to label goods with information including indications that the goods have fulfilled requirements set in the Ethiopian standards.[68]

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[57] narcotic drugs are defined as a medicine subject to control in accordance with the Convention issued by United Nations and ratified by Ethiopia and include a drug that is categorized as narcotic drug by the Regulator.

[58] Psychotropic substance is defined any substance subject to control in accordance with the Convention issued by United Nations and ratified by Ethiopia and include a drug that is categorized as psychotropic substance by the regulator.

[59] A detailed list of criminal liability and subsequent penalty for actors in the food and drug sector is presented under article 67 of the Food and Medicine administration proclamation.

[60] Public Health Proclamation 200/2000. The law under article 2(5) defining health both as the absence of disease and the complete social, physical and mental wellbeing of an individual has envisioned a wider horizon for the conception of health. Also note that the country has a law governing public health as early as 1942.(Proclamation 26/1942 Public Health Proclamation)

[61] Art 8 of PHP

[62] Art 9 of PHP

[63] Art 10 of PHP

[64] Elias N.Stebek (2018) *Consumer Protection Law in Ethiopia: The Normative Regime and the Way Forward*, Journal of Consumer Policy 41; PP. 309–332. This article is worth a read for the brief presentation of consumer right from different legal regimes in Ethiopia. The author points out various practical challenges that face the current consumer protection law.

[65] Trade Competition and Consumer Protection Proclamation, Proclamation No 813/2013, Preamble. Article 3(2) of the law reinstates this same theme as objective of the proclamation.

[66] TCCPP Art 2(1) defines goods as movable commodities on market incorporating food and drugs to the definition.

[67] Art 22(10) of TCCPP

[68] Art 16(1) (2(l)) of TCCPP

In relation to food safety, the animal disease prevention and control proclamation(ADPCP) has a food regulatory element as it contemplates measures to the effect of prohibiting and controlling the importation of animal products;[69] animal by-products from areas or countries infected or suspected of being infected by animal disease, prohibit and control the movement of animal products and by-products from regions infected or suspected of being infected by animal disease to other regions in the country or out of the country.[70]

The Ministry of Agriculture, by law, is explicitly duty bound to set priorities for the control of animal diseases based on their socio economic and public health impact and implement control programs.[71] Animal movement permit[72], entrance permit for importing animal products[73], quarantine controls established for animal product export[74], sanitary and health certificates[75] are all some manifestations of the regulatory power of the state incorporated in the ADPCP in connection to food regulation.

The live animal marketing proclamation (LAMP) is another law concerned with food regulation. The law governs the marketing of live animals for both local and export market.[76] The law calls for a mandatory pre - marketing health checks on animals planned to be on the market by relevant organs.[77] It also mandates pre - purchase health and quality control of live animals.[78] By enlisting specific requirements of duties on major parties to the live animal market i.e. the abattoir operators[79], butchers[80], animal transporters[81], feedlot operators[82] and exporters,[83] it establishes a quality element and thereby protect any possible damage on the safety of consumers of final products of the trade.

A detailed governance of regulation of the food and drug sector is the ambit of the Food and Medicine Proclamation (FMP). Although a multitude of other laws have a regulatory impact on food and drugs, the principal law of such instance is the FMP. The preamble of the food and

[69] Animal product is defined in the proclamation to include meat, meat products, milk products, egg, honey and other which all fall in the food category making any regulatory act in connection to this product with the concern of health and safety of consumers a food regulatory law.
[70] Animal Disease Prevention and Control Proclamation NO. 267/2002 Article 7(1_3)
[71] Art 7(9) of ADPCP
[72] Art 15 of ADPCP
[73] Art 13 of ADPCP
[74] Art 12 of ADPCP
[75] Art 14 of ADPCP
[76] Live Animals Marketing Proclamation No. 819/2014, preamble.
[77] Art 7(2) of LAMP
[78] Art 11(4) of LAMP
[79] Art 13 of LAMP
[80] Art 14 of LAMP
[81] Art 12 of LAMP
[82] Art 10 of LAMP
[83] Art 11 of LAMP

medicine proclamation states the reason that necessitates the law as a means to the prevention and control of public health.[84]

It is also explicitly stated that regulatory scheme installation which responds to the nations industry and manufacturing sector is one of the reasons that call for the promulgation of the law.[85] The degree and intensity of regulation was directly linked with the proportion of the potential risk the regulated product is likely to have on human health.[86] This strengthens the justification provided for regulation of food and drug sector being primarily public health concerns.

The scope of the law is articulated to encompass a much wider realm inclusive of the food and drug market.[87] The proclamation is applicable with respect to food and medicine intended to be placed on the market or offered in any other way for use by the public.[88]

The term food as to the law encompasses salt, water and alcohol,[89] to the exclusion of cosmetics, tobacco and medicine.[90] Hence the scope of the law is wider under the food term to regulate the bottled water and alcohol industry on top of the ordinary understood food market.

The spectrum of regulation extends from a mere concentration to market provided food and medicine via normal channels of business to the provision made by any entity through any means. [91] Food and medicine fall in the category of regulated product by the law among other products.[92]

The Ethiopian Food and Drug Authority (EFDA) is the national regulatory body for food and drug quality, safety and efficacy in Ethiopia.[93] Operational as of July 2010, a fairly young institution since its reorganization and establishment, it has the objective of protecting the health of the consumer by ensuring food safety and quality plus by ensuring safety, efficacy , quality, and proper

[84] Food and Medicine Administration Proclamation No.1112/2019, Preamble. Note how the law uses the term medicine instead of drug. Accordingly, we will use drug and medicine interchangeably with same meaning.
[85] Ibid. The preamble closes by stating the need to adopt a national legal framework which enables establishment of a coordinated food and medicine regulatory system. This statement is a clear indication as to how the law is meant as a measure regulator of the industry.
[86] Art5 (2),13(2) of FMAP
[87] Art 3 OF FMAP. The law is divided in to the following core sections- Art5-8 Food Safety administration, Art 19-41 medicine, medical device and cosmetics administration, Art 46-52 tobacco and related products administration, Art 53-62 labelling, packaging, adverts and promotion, Art 63-64 powers functions and responsibilities of inspectors, Art 65-67 administrative measures and penalties.
[88] Ibid.
[89] Alcohol is any drink with volume of more than 0.5% alcohol content. Art 2(41) of FMAP.
[90] Art 2(2) of FMAP. Sub article 9 of this same provision defines medicine as any substance or mixture of substance used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof used in restoring, correcting or beneficial modification of organic or mental functions in human; or articles other than food, intended to affect the structure or any function of the body of human and it includes articles intended for use as a component of any of the above specified articles.
[91] The distinction made between food trade establishment and food establishment where by the former is linked with market providers primarily working for profit and the latter to any other provider inclusive of food trade establishment is also in tune with this wider scope. (See Article 2(2) (3) of FMAP
[92] Art 2(44) of FMAP
[93] www.fmhaca.gov.et When the FMAP speaks of an executive organ under Article 2(57) as the body empowered to administer the proclamation the reference is to the Ethiopian Food and Drug Authority.

use of medicine.[94] Primarily engaged in the tasks of standard initiation, quality control, license issuance, and inspection undertaking, the authority is the principal organ in the food and medicine regulatory task.[95]

In connection to foods, the law contemplates a pre-market and post - market regulatory procedure.[96] The pre-market regulation includes standard setting[97], compulsory registration[98], and safety requirement compliance[99], information provision[100] requirement related to personnel working in the food industry[101], installation of quality control system[102], mandatory licenses and health certificates[103] and securing prior authorization for certain acts.[104]

Once the regulated food product is on the market the post market regulation sets in in a form of continuous safety monitoring.[105] The regulation which expands the principles and rules enshrined under the proclamation explicitly states
"*No food unfits for human consumption or not complying with appropriate safely and quality standards may be manufactured. Imported, exported, stored, distributed, transported or made available for sale or use to the public.*"[106]

For regulating medicine[107] the law makes any act[108] in connection to medicine to be legitimate only when it is registered and secures market authorization by the regulator.[109] Certificate of registration Market authorization will be provided by the regulator up on the fulfillment of the following conditions ; a) assuring the medicine manufacturer's compliance to good manufacturing

[94] Ibid
[95] Ibid
[96] The wording post market regulation is located in the law see Art 17 FDAP. Hence this paper uses pre market regulation for all the other regulatory provisions incorporated in the law although at times there may be an overlap in time framework of regulation for some type of regulations.
[97] Art 5(2), 11,12,14 of FDAP
[98] Art 6(1),13 of FDAP
[99] Art 7 of FDAP
[100] Art 7(6) of FDAP
[101] Art 8 of FDAP
[102] Art 9 of FMAP
[103] Art 10 of FMAP
[104] Art 6(2) of FMAP
[105] Art 17(1)(2)(3) of FMAP
[106] Art 3 of REG 299/2013. Note that this regulation was made on the basis of the former Food and Drug law which was replaced by the current FDAP. Yet its application is still in place as to article 71 of FMAP which empowers the council of regulation to make regulations. Furthermore Art 70 of FMAP which make a repeal of proclamation 661/ 2009 makes no mention of Regulation 299/2013 except a wording as to the non-applicability; of any regulation which is inconsistent with the FMAP. Hence until a time for a new regulation to the application of FMAP the regulation remains intact for major parts of the law.
[107] The law that was repealed by FMAP under discussion has defined medicine to include medical devices/ medical instruments, SEE Art 2(6) of Proc 661/2009 Food, Medicine and Health Care administration and control proclamation. FMAP has separated medicine from medical device from the definition and in subsequent substantive parts of the law.
[108] See how wide the scope is as manufacturing, importing, exporting, storing, distributing, transporting, selling, holding, using and transferring are listed acts that require registration and market authorization.
[109] Art20 of FMAP

practice; b) the medicine dossier is evaluated and found to fulfill safety, quality and efficacy requirements; and c) the medicine fulfill laboratory quality test requirements.[110] Hence the core criteria for registering and allowing market authorization are the quality, safety and efficacy of the medicine.[111]

The regulation in this regard states "*No medicine the quality, safety and efficacy of which is not ascertained may be manufactured, imported, exported, stored, distributed, transported or made available for sale or use to the public*."[112]

Special Emphasis on Regulatory Provisions

A mere look at article 4 of FMAP reveals the wide power of regulation provided for the executive organ i.e., EFDA and delegated regional bureaus. To start with the organ has a power of initiation and implementation of regulatory standards regarding food safety and the safety, efficacy, quality and rational use of medicine.[113]

Here one needs to notice how the organ is endowed with the power of initiating regulatory standards. Though the Ethiopian Standard Agency is the sole standard setting body of the nation it is normal for concerned government and non-government bodies to participate in the process.[114] It is in this aspect the EFDA is empowered by the law to initiate a standard.

On the aspect of implementation of standards different regulatory power is stipulated. To start with EFDA is with the power to evaluate and register food and medicine.[115] Here the evaluation and registration pertains to the fulfillment of standards set by the responsible organ and plays an information role to third parties and society at large as to the type of regulated product allowed to be in the market.[116]

One of the common modalities of regulation is entry regulation[117]. By listing requirements of different sort, the regulatory power ensures who the actors in the market are. This control is mainly attributed with an economic regulation dimension of competition[118]. It is also possible to pin point

[110] Art 15(4) of REG 299/2013
[111] Ibid.
[112] Art 14 of REG 299/2013
[113] Art 4(1) of FMAP
[114] ESA (2019) Compulsory Ethiopian Standards, The Ethiopian Standards Agency (ESA) is the national standards body of Ethiopia established in 2010 based on regulation No. 193/2010.ESA is established due to the restructuring of Quality and Standards Authority of Ethiopia (QSAE) which was established in 1998. The Ethiopian Standards are developed by national technical committees which are composed of different stakeholders consisting of educational Institutions, research institutes, government organizations, certification, inspection, and testing organizations, regulatory bodies, consumer association etc.
[115] Art 4(3) of FMAP.
[116] Art 4(8) of FMAP. The organ will have a power to notify registered food and medicine to the public.
[117] Shirley Svorny (1999) Licensing, market entry regulation, P.298 accessed at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.597.2765&rep=rep1&type=pdf
[118] Ibid.

its social aspect as the entry restrictions are standards set which must be fulfilled by whosoever wants to join the sector and the standards have explicit public interest justifications.

The FMAP empowers the regulatory power with determining entry to the food and medicine market. It is this organ which issues import permit and provide export certificate on demand[119] for regulated products. It is also this organ which issues, renews, suspends, revokes certificate of competence, market authorization for importers, exporters, manufacturers, wholesalers, retailers of food and medicine products.[120] Every food establishment must be registered with the regulator to start operation.[121]

Accordingly, the organ has a power to restrict the type of actor who is to engage in the sector as long as such is done as to the due process of regulatory law in place.[122] A careful study of the provisions listing the powers of the regulatory organ shows that a grey area of power is purposely left to the organ leaving it with discretion of taking almost any measure below the sun to the actors in the food and medicine sector.[123]

In combating the information asymmetry that is in place in the food and medicine industry and the consumer regulation plays a prominent role.[124] Labeling and packaging are the primary instruments in this regard.[125] Other than calling for appropriate and standard packaging[126] of foods and medicines the law requires the primary packaging of packed food to be in Amharic or English or another language set by the authority. [127] Also, the insert labeling of a medicine shall be in

[119] Art 4(7) of FMAP
[120] Art 4(2) and (3)(13) of FMAP
[121] Art 6(1)(2) of FMAP
[122] In the spirit of a regulated free market, the law does not go to the monopoly of market power or to the exclusion of private actors from the sector. In fact, article 19(2) of the FMAP explicitly refrains from the act of limiting the number of agents a manufacturer may designate for purpose of importing and distributing medicine. Though a similar provision does not exist in the food sector the lack of clear prohibition to similar effect is interpreted as endorsement of free market and competitive industry. Furthermore, a study conducted by the United Nations with emphasis on some food sectors of Ethiopia like coffee, livestock and beer has assessed the interlink between competition and regulation and stated, the interaction of sector regulation and competition law and policy is not only unavoidable but is also necessary. (SEE UNCTAD (2018) A REVIEW OF COMPETITION POLICY IN ETHIOPIA, NEWYORK AND GENEVA P.60)
[123] Art 4(2) (3) (4) (5) (6) of FMAP contain a phrase '' take another appropriate measure' '' take other appropriate legal measure'' '' take such other legal measures'' 'the necessary administrative measures" and '' take appropriate legal measures" These terms leave a wide space to the 'regulatory organ to take measures which other parties may take as abuse of power. The immediate legislation of relevant regulations and directives listing these measures so far as they can be forecasted is one mechanism to counter such doubt between the regulator and the regulated.
[124] Melese Temesgen and Melese Abdisa (2015) *Food Standards, Food Law and regulation system in Ethiopia: a Review*, public policy and administration research, p 62
[125] John M. Antle (1996) *Efficient Food Safety Regulation in the Food Manufacturing Sector*, American Journal of Agricultural Economics, 78, 5; P 1244. The Author puts labelling and product certification as remedies for the information asymmetry problem. Art 2(46) (47) of FMAP define what packaging and labelling means in the Ethiopian legal context.
[126] Art 5(3), 53(1) of FMAP
[127] Art 53(2) of FMAP. For a detail account of food labelling see art 54 of FMAP.

Amharic or English unless the medicine is intended to be sold in one region calling for state language.[128]

In a regulation meant to apply on the operation phase of the industries Article 4 of the law mention inspection of regulated product and the industry. [129] Actors are ordered by law to establish quality control system[130] which is intended to ensure a product meets quality and safety. This system includes ensuring the cleanness and contamination free operation areas of food establishments[131], mandatory provision of information about the nature of food provided.[132]

As part of the post marketing surveillance stated under sub article 9 of article 4 the regulatory organ is empowered to detain, seize, confiscate, and order the disposal or the recall of a regulated product which is not in compliance with set standard and requirement[133]. By ordering every food and medicine manufacturer and importer to employ a safety of their products and employing a continuous system of safety to the extent of informing the public at large not to use the product and recall same regulation has continued the marketing phase of the food and drug sector.[134]

It is also the power of the organ to identify an ingredient that has caused death, sickness, disability, disorder, or other health problem once such issue surfaces with the intention of taking appropriate measures.[135] The regulator is also mandated to regulate cross regional advert of regulated products.[136] Advertisements of any sort have an impact of persuading consumers to use the product on display.[137] The law that governs adverts in Ethiopia has explicitly prohibited the advertising of certain food and medicines.[138] The FMAP in principle prohibits the advertisement of medicine.[139] It also incorporates a very strict regulation on alcohol advertisement as it bans any such act through broadcast of any sort.[140]

One last point worthy of discussion in food and drug regulation is the capture theory of regulation. In an effort that seems to address this issue, the FAMP has this to say under article fifty-one:

[128] Art 53(3) of FMAP. For a detail account of medicine labelling see art 56 OF FMAP
[129] Art 4(18) of FMAP. The law takes the inspection as an important regulatory tool it even empowers the regulatory power to execute inspection by entering a site without court order under certain cases.
[130] Art 9(1) of FMAP
[131] Art 7 of FMAP
[132] Art 7(6) of FMAP
[133] Art 4(4) of FMAP, Art 31 &32 of REG 299/2013.
[134] Art 17 of FMAP & Art 38 of FMAP
[135] Art4(6) of FMAP
[136] Art4(14) of FMAP
[137] This seems the motivating factor for the FMAP to draw a joint and several responsibilities for the advertiser and the advert disseminator to respect the rules in place or any other appropriate directive to be issued accordingly concerning advert and promotion of food and medicine. Art 58(3) of FMAP.
[138] Advertisement proclamation No. 759/2012 Art 25(1) a-c
[139] FMAP Art 59
[140] See the detail restriction under Article 60 of the FMAP

'*Interactions between any government organs responsible for the adoption of public health policy and the tobacco industry shall be limited to only those strictly necessary for effective regulation of the tobacco industry or tobacco products*.''

The absence of such explicit provision in the food and medicine sector will create the assumption that such stand of the law in the clear separation between the regulatory agency and the regulated. The remaining sub articles has expanded the provision under sub article 1 and 2 further claiming any interaction made in accordance with sub-article (I) of this article, and whenever the tobacco industry contacts the government to initiate an interaction of any kind, the appropriate government official shall ensure full transparency of the interaction and of the contact, and it shall be appropriately documented.

To substantiate the transparency element the law goes further and states that no person having financial or other interest in the tobacco industry may participate in tobacco control training, workshop, or related events unless in accordance with an invitation by the relevant health regulator. Further no government organ or an official working in the area of health policy should receive any financial or in-kind contribution from the tobacco industry. A government organ may receive contribution from the tobacco industry in accordance with sub-article 5 of this same provision. Any financial or in-kind charitable or any other related contribution by a tobacco industry is prohibited.[141]

It is necessary to avoid not only actual conflict of interest but its appearance and narrow the entire door for potential conflicts by stating the stand of the law and empowering the regulator with legal basis to stop the interference of powerful industries or their coalition from influencing policy direction and regulatory objectives and directions.

Conclusion and Recommendations

The article has shown that the food and drug regulation in Ethiopia, both economic and social, has a constitutional and legal basis. The constitution of FDRE has given the Federal Government the power to make laws on issues concerning public health. As the primary regulatory justification of food and drug is related to health, it helps in establishing the constitutionality of the regulation constitutional.

The sub constitutional norms on the regulation of food and drug are found scattered in different piecemeal legislations. Although the recent food and medicine administration proclamation is the primary law in this aspect, it is not exhaustive and a cross-reference to various other laws is needed to get the full picture of the legal basis of regulation.

It is, therefore, necessary to have a compiled food and medicine policy and code to facilitate the effective regulation of the industry. This will also help the harmonization process of regulation of the sector that is in place by different concerned organs. The combined efforts put together by the

[141] Ibid.

various organs which have legislated directives of various sorts in helping the implementation of regulating the food and drug sector is a must and concerned parties must find time and place to come together and consul on the way forward for a harmonized regulatory framework.

Ethiopia's regulatory framework is not free from the fear of regulatory capture. There is a risk of public interest justification of regulation being set aside by giant corporations and their unions. The desire to attract investment and the justified need for poverty reduction may play a negative role regarding the sincerity of the regulatory powers. Such is then practical concerns the existing legal framework might face calling for a legislative solution. The solution must take into account the balance between the ever-increasing needs of development with the health and safety of its citizens to whom development is planned and promised.