

Research Article

Partisan Impacts and Determinants for Internationalization of Ethiopian Pharmaceutical Products

Guyassa Daniel Waktole¹, Tefera Tezera Negera^{2, *}

¹Department of Management, LIGS University, Hawaii, USA

²Department of Pharmacy, Rift Valley University, Addis Ababa, Ethiopia

Abstract

Background: The pharmaceutical and related commodities manufacturing industry in Ethiopia is long-lived because the country is well-endowed with basic raw materials and local ownership and to some extent with machinery and technological know-how. The pharmaceutical industry, both globally and in Africa, encounters challenges in internationalizing products. In Ethiopia, challenges like regulatory complexities and limited government support hinder international market access for pharmaceutical products. This aim is to explore the barriers and understand why Ethiopian pharmaceuticals struggle to enter global markets. **Method:** The study adopted a mixed research approach, integrating qualitative and quantitative methods. It focuses on 15 pharmaceutical industries in Ethiopia, particularly those in Addis Ababa and the Oromia Special Zone, using probability and none probability sampling technique. The total study participants involved in the quantitative and qualitative studies were 373 and 15, respectively. Data collection comprises questionnaires, key informant interviews, and observation checklists, supplemented by secondary data from official and theoretical sources. Ethical considerations underscore obtaining verbal consent and ensuring confidentiality. Analysis entails descriptive statistics and qualitative synthesis, with numerical analysis conducted using STATA 14.1 software. **Results:** Out of the expected 384 study participants, 373 (97.13%) participated in our study, while the entire group of participants proposed in the qualitative study (15) also participated in this study. Key findings include resource constraints, regulatory issues, and biased perceptions against local products, hindering their global recognition. While strong political commitment and effective policy enforcement at the top government level are crucial, inadequate collaboration across government tiers undermines these efforts. Despite existing policies, inadequate implementation and procedural guidance diminish industry interest. There's uncertainty about government support for local pharmaceutical production, with persistent challenges like resource shortages and policy inconsistencies impeding progress. Perceptions vary on the effectiveness of policies promoting local production, and concerns about taxation issues impact the industry. Nevertheless, most respondents' express confidence in the quality of domestically produced pharmaceuticals. **Conclusion:** Despite crucial government commitment, weak collaboration across levels impedes progress. Respondents note deficient policy implementation and doubt government support. Persistent issues like resource shortages persist, along with taxation concerns, despite locally produced products being perceived as equal in quality. To advance, better policy implementation, regulatory harmony, financial support, infrastructure enhancement, increased awareness, and improved collaboration are essential.

Keywords

Challenges, Ethiopia, Harmonization, Internationalization, Partisan, Pharmaceutical

*Corresponding author: tefera_tezera@yahoo.com (Tefera Tezera Negera)

Received: 4 September 2024; **Accepted:** 23 September 2024; **Published:** 18 October 2024



Copyright: © The Author(s), 2024. Published by Science Publishing Group. This is an **Open Access** article, distributed under the terms of the Creative Commons Attribution 4.0 License (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution and reproduction in any medium, provided the original work is properly cited.

1. Introduction

The pharmaceutical and related commodities manufacturing industry in Ethiopia is long-lived because the country is well-endowed with the basic raw materials and local ownership and to some extent with machinery and technological know-how [1]. Export of products from pharmaceutical industries in Ethiopia grew at an average annual rate of 19% in value terms and 6.1% in volume terms. However, given the low starting base, their share in total exports remained around 0.5% during this period [2].

The global landscape is constantly evolving due to resource scarcity, prompting the need for globalization and internationalization to optimize resource utilization. In this globalized world, regulatory frameworks must resolve to ensure the safe and effective supply of medicines, a growing global priority [3].

In the case of Ethiopia, the internationalization of pharmaceutical products is almost none [4] and a case study done in Kenya revealed that the pharmaceutical marketing industry is no exception and has also been affected by several challenges [5].

Developing-country multinational enterprises are on the rise, indicating distinctive approaches to internationalization [6]. Internationalization involves conducting business activities across borders and overcoming various challenges such as structural, operational, and attitudinal constraints [7].

The global pharmaceutical industry faces challenges like economic shifts and limited access to affordable medical products, particularly in smaller economies like those in Africa. Similar to this trend, Ethiopian industries struggle to export their products due to a lack of government policies and implementation plans and existing policies to promote the sector, have not been effectively executed in the recent years [8].

Challenges in the pharmaceutical industry include globalization pressures, loss of local market value, and intense innovation [9]. Insufficient access to quality medical products in Africa is attributed to weak policies and regulatory systems. Government policies, training, and compliance are crucial for successful pharmaceutical production [10].

Ethiopia possesses a sizable and growing domestic pharmaceutical market valued at \$684 million in 2018. However, imports account for approximately 85% of this market. Pharmaceutical manufacturing is a nascent industry, with only a few of the nine local manufacturers being Good Manufacturing Practices (GMP) certified. Out of 380 essential medicines, less than 90 are produced locally, seeing limited uptake compared to imported drugs supplied by over 200 importers. Despite these challenges, significant opportunities exist for sector growth, potentially promoting import substitution, export diversification, and improved access to essential medicines. The Ethiopian government is currently keen on establishing a pharmaceutical manufacturing hub by launching the Kilinto Pharmaceutical Industrial Park [11].

Ethiopia's pharmaceutical industry struggles with limited

international presence due to challenges like unreliable electricity, costly telecommunications, and inefficient transportation [12]. Despite abundant raw materials and some local ownership, the sector faces barriers to internationalization [13, 2]. Motivations for international trade include government support and access to regional and international markets. However, barriers such as inadequate infrastructure, bureaucratic hurdles, and capital shortages hinder the manufacturing sector's growth [14]. Despite efforts to promote local pharmaceutical production, challenges persist, including regulatory issues and limited capacity [3].

Regulatory linkages and limited sector-wide engagement affect pharmaceutical export performance, with challenges including registration requirements and regulated promotion campaigns. Local pharmaceutical manufacturers in Ethiopia face significant challenges in internationalization despite efforts to expand their market reach [15].

Addressing these challenges can benefit developing countries' economies and contribute to meeting Sustainable Development Goals (SDGs) through more efficient regulatory systems [3, 8]. Therefore, the study relevant for policymakers, stakeholders, and pharmaceutical industries to understand challenges and develop strategies for policy modifications is not adequate to inform policy [14]. Hypotheses are proposed regarding the internationalization potential of Ethiopian pharmaceuticals, government support, public attitudes, industry decline, and policy harmonization with specific objectives including identifying barriers to promotion and recognition in international markets, assessing government support, evaluating public attitudes, and examining regulatory harmonization efforts. The research aims to uncover factors affecting internationalization, partisan impacts, and challenges facing Ethiopian pharmaceutical products. Additionally, it serves as a resource for future research on related topics.

2. Methods

2.1. Study Setting, Design, and Period

Research design is a logical model of proof that allows the researcher to draw inferences concerning causal relations among the variables under investigation [14-16]. This study employed a mixed research approach, utilizing both qualitative and quantitative research methods. The overall approach leaned towards qualitative methods.

2.2. Study Population

As of September 16, 2023, Ethiopia's estimated population is 127,192,245 (World meter, 2023). This constitutes 1.57% of the global population. According to United Nations Economic Commission (UNECA, 2022), 22.1% (27,959,894 people)

reside in urban areas, with a median age of 18.8 years. The study is conducted in Addis Ababa city and Oromia region. Addis Ababa is the capital of Ethiopia, is its largest city and sits on the Ethiopian highlands. Governed by the federal government, it has a population of around 5.5 million as of 2023. Meanwhile, the Oromia Regional State (ORS), bordering various regions including Somalia and Kenya, covers a vast area of 353,690 square kilometers.

2.3. Sampling Technic and Sample Size

The study employed a sampling frame to identify the target population. During the data collection period, all pharmaceutical industries, pharmacies, wholesalers, importers, and relevant government offices in Addis Ababa City Administration and ORS were considered as the target population.

A two-pronged sampling approach was used

Non-random sampling. This method was applied to select the pharmaceutical manufacturers and key stakeholders (government officials). The rationale behind this choice was to ensure the inclusion of all twelve pharmaceutical industries located in the study areas and to target specific government representatives with expertise in pharmaceutical regulations and international trade.

Simple random sampling This method was used to select respondents from retail pharmacies, wholesalers, and importers within the study areas. This approach ensured that all establishments within this category had an equal chance of being selected.

Sample Size

Sample Size for Retailers, Wholesalers, and Importers

Due to the unknown number of retail pharmacies, wholesalers, and importers in the study areas, the sample size calculation considered the following factors.

Confidence level 95% ($z = 1.96$)

Desired margin of error 0.5

Estimated population proportion (p) with the characteristic of interest 50% (assuming equal distribution)

Using the following formula

$$n = \frac{z^2 XpX(1-p)}{d^2}$$

where

n = required sample size

z = z-score

p = estimated proportion with the characteristic

d = margin of error

The calculated sample size for retailers, wholesalers, and importers was 384.

2.4. Inclusion and Exclusion Criteria

2.4.1. Inclusion Criteria

1) All pharmaceutical industries in Addis Ababa City

Administration and Oromia Regional State, regardless of size, establishment year, or investment level.

2) Heads or designated representatives of relevant government stakeholder organizations.

3) Retail pharmacies, wholesalers, and importers of pharmaceutical products operating within the study areas.

2.4.2. Exclusion Criteria

1) Pharmaceutical industries located outside of Addis Ababa City Administration and Oromia Regional State.

2) Pharmaceutical industries under establishment.

3) Retail pharmacies, wholesalers, and importers outside of the study areas.

4) Pharmaceutical industries producing raw materials or other inputs for pharmaceutical products.

2.5. Data Collection Methods and Data Quality Control

2.5.1. Data Collection Methods

The study employed a multi-strategy approach to collect data, utilizing both primary and secondary sources.

2.5.2. Primary Data Collection

Self-administered and semi-structured questionnaires These were distributed to employees of retail pharmacies, wholesalers, and importers. The questionnaires were designed to gather data on their experiences and perspectives regarding the internationalization of Ethiopian pharmaceutical products.

Key informant interviews (KIIs) In-depth interviews were conducted with heads of relevant government bodies to gain insights into policies, regulations, and initiatives related to pharmaceutical exports.

Checklist This tool was used to record observations on the quality control practices, production systems, and export efforts of the participating pharmaceutical industries.

2.5.3. Secondary Data Collection

Official statistical and theoretical sources. This included publications, regulations, reports, and documents from government agencies, industry associations, and research institutions.

Academic literature Books, journals, and online resources provided valuable background information and theoretical frameworks relevant to the study topic.

2.5.4. Data Quality Control Measures

Several steps were taken to ensure the quality and trustworthiness of the collected data.

The questionnaires were pilot-tested with a small group of respondents to assess clarity, comprehensiveness, and ease of use. Based on the feedback, refinements were made to the questionnaires before full-scale data collection.

Interviewers for the KIIs received training on conducting

ethical and effective interviews, ensuring consistency in data collection. Consistent coding schemes were applied to qualitative data from interviews and observations. Additionally, verification procedures were implemented to minimize errors in data entry and analysis.

2.6. Data Analysis

Data was collected from May 2023 to July 2023, across three months after pretesting the data collection tools. The study identified factors hindering the internationalization of Ethiopian pharmaceutical products focusing on manufacturers, stakeholders, retailers, wholesalers, and importers in Addis Ababa and Oromia. A high response rate (nearly 97.4%) was achieved for the questionnaires distributed to these various respondent groups. To assess the data's reliability, Cronbach's alpha was employed. The score of 0.899 indicated good internal consistency. The data from each respondent group (manufacturers, stakeholders, retailers/wholesalers/importers) were analyzed and interpreted separately to gain deeper insights.

SPSS and STATA software (versions 26 and 14.1) were used to perform these analyses. A Cronbach's alpha of 0.899, indicating good internal consistency, was achieved for the quantitative data. Outliers were removed, and incomplete information from questionnaires was addressed.

Descriptive statistics (frequencies, percentages) were used to understand the distribution of responses. Cross-tabulations helped identify relationships between variables. Correlation analysis measured the strength of association between variables. Regression analysis assessed how one variable influence another, while mean analysis calculated average values. Various statistical models to analyze the data including frequencies, cross-tabulations, bivariate and 2-tailed Pearson correlation, and ordinal and binary logistic regressions were also used with a primary goal of identifying key factors hindering the internationalization of Ethiopian pharmaceutical products and to examine the relationships between these factors.

3. Results

3.1. Sociodemographic Characteristics of the Respondents

Among a total 12 pharmaceutical with 384 respondents had at least a bachelor's degree. The nationality breakdown for each respondent group revealed a mix of Ethiopians (62.5%) and foreigners (37.5%) in the pharmaceutical industries, with more foreign investment observed in Addis Ababa compared to Oromia. Interestingly, all respondents in the importers/wholesalers/retailer's category were Ethiopian, and most were concentrated in Addis Ababa (55.76%). The stakeholder group consisted of Ethiopians (80%) and foreigners (20%),

with more concentrated in Addis Ababa as well. This data suggested there might be challenges attracting foreign investment in pharmaceutical industries located outside of Addis Ababa.

The demographic characteristics of the respondents were taped to look for the gender mainstreaming effects and active participation of foreign experts in the development endeavors of pharmaceutical products development in Ethiopia. Furthermore, the analysis of these data helps the researcher to further investigate opportunities for local manufacturers to work in partnership with international companies and expats.

3.1.1. Sex to Educational Status of Respondents

Analyzing the sex to the level of education distribution of the respondents has paramount benefits to dealing with the need of skilled and semi-skilled needs of the sector beyond the existing demand and employment of international expats.

3.1.2. Manufacturer Respondents (MRs)

Among manufacturer respondents, 19 respondents (13 male and 6 female) held a bachelor's degree, while 5 (4 male and 1 female) held postgraduate degrees. In terms of marital status, the majority (20 respondents - 15 male and 5 female) were married.

3.1.3. Importers/ Wholesalers, Retailers Respondents (IWRRs)

Among Importers/Wholesalers, Retailers Respondents (IWRRs), the majority (222, which is 59.52%) of IWRRs were undergraduates, followed by diploma graduates accounting for 145 (38.87%) of the total IWRRs.

3.1.4. Stakeholder and Partner Respondents (SPRs)

Among the 12 SPRs, 2 were female - one undergraduate and one widowed postgraduate. The remaining 83.33% of male respondents included 8 who were married.

3.2. Respondents and Year of Establishment of Pharmaceutical Industries

The average age of MRs was 40.67, with an average of 16.83 years of experience. The mean year of establishment for the pharmaceutical industries where respondents were employed was 2000.5, indicating that most of these industries were established between late 1999 and the beginning of 2000. Similarly, the average age of IWRRs was 35.59, with an average work experience of 12.03 years. SPRs had an average age of 42, ranging from 28 to 67 years old (Figure 1).

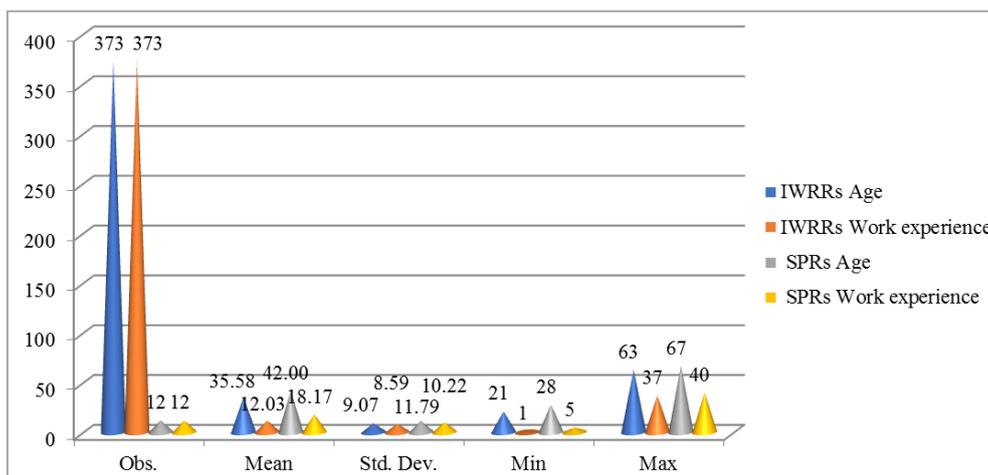


Figure 1. Age and Work experience of Respondents.

3.3. Factors That Affect the Internationalization of Pharmaceutical Products

According to KIIs, respondents, factors affecting the internationalization of locally produced pharmaceutical products face obstacles in internationalization due to a combination of internal and external factors. Internally, limitations such as inadequate human capital, technology, financial resources, and supportive industries hinder progress. Additionally, weak policy implementation, negative perceptions about Ethiopia, and lack of government support and cooperation deter local pharmaceutical industries from expanding globally.

Internationalization barriers encompass both internal and external constraints that inhibit firms from initiating or expanding export activities. These barriers often stem from a

lack of regulatory cooperation, policy harmonization, strategic resources, and access to financial support. Additionally, biases against local products and insufficient bank credit further complicate the process [9].

Respondents of the KII have noticed the causes of those identified key challenges and the impacts on their businesses. As the KII respondents’ revelations, the lack of cooperation and coordination by stakeholder and the weak capacity of regulatory authorities making delayed and rigid decisions has brought the kicked-out of the local industries from the market as well as to be unable in cope-up the present globalized market competitions impeding the ability of local industries to compete in the global market and meet WHO standards for internationalization.

The results reveal several key factors hindering the internationalization of locally manufactured pharmaceutical products (Table 1).

Table 2. Result of logistic regression analysis – Challenges in Internationalization of Pharmaceutical Products (PP).

Explanatory variables	B	S.E.	Wald	df	Sig.	Exp (B)
locally produced medicines and related commodities have equal quality with imported ones	-.235	.819	.082	1	.774	.791
Step 1 ^a Having local EFDACGMP	-19.455	14072.647	.000	1	.999	.000
export of any products	-.733	1.097	.446	1	.504	.481
Constant	42.282	28145.294	.000	1	.999	.000

a. Variable(s) entered on step 1: Do you think that locally produced medicines and related commodities have, Does your company have Local EFDACGMP, Does your company export any of its products so far.

3.4. Policy Challenges

Government’s Political Commitment and Policy Enforce-

ment

The respondents of the KII perceived the existing policies regarding the production, promotion, and sale of pharmaceutical products as hit-or-miss. The absence of these instigating

the policy and its next procedures discourages the local industries from doing their best and compels the industries to encounter multiple challenges to internationalize their pharmaceutical products.

Government political commitments at every level and the appropriate policy formulations as well as enforcement are among the mandatory issues for the internationalization of pharmaceutical products. Indeed, the majority (n=242, 64.88%) of respondents from the manufacturing firms revealed that the uppermost level of the government has no political commitment to the local production of pharmaceuticals and related commodities.

Most (n=242) IWRRS have thought that there is not either a strong political commitment or there is not strong collaboration and coordinated efforts among the highest government level for local production of pharmaceuticals and related commodities as shown in (Figure 2) below.

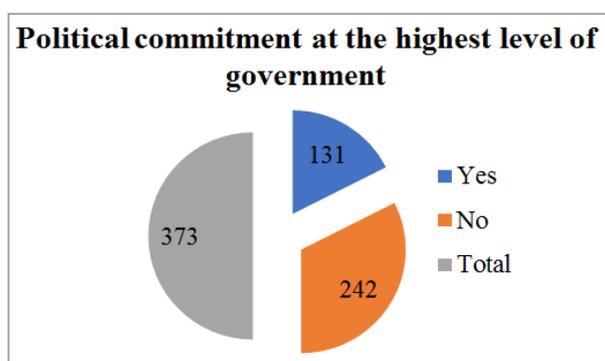


Figure 2. Existing Political Commitment for the internationalization of products.

The political influence of the “race to the bottom” (RTB) imagery has been considerable. It informs much of the recent opposition to globalization in general and trade liberalization in particular [17].

The political commitment of the government to support the industries and make them capable of promoting their products to the world and partaking in the international market has an impact on the products being restricted to the local markets and lack of international recognition of their healing effectiveness and quality. The respondents about the lack of foreign currencies and the need for huge capital to run the business divulged the shortage of raw materials and other inputs to produce the pharmaceutical products and related materials.

The strong political commitment was checked for the

availability of strong collaboration and coordination efforts of the government at the highest level. As a result, four of the respondents from partners and stakeholders have said that there is strong political commitment and coordination as well as collaboration efforts of the government at the highest level. An equal number of respondents to this has said also there is a strong political commitment of the government at the highest level while there is no strong collaboration and coordination effort at the same level of the government.

3.5. Collaborations and Coordination at Different Levels of Government

Strong collaboration and coordination among government levels significantly impact the internationalization of pharmaceutical products, as indicated by statistical analysis. Weak collaboration efforts at various government levels hinder the industry's ability to expand globally.

Discontent over globalization arises from neglecting certain population groups affected by integration, leading to rising unemployment and economic dislocation. Policy measures aimed at aiding affected communities have largely failed due to policymakers' misunderstanding of the costs borne by workers and firms.

While coordination and collaboration efforts at lower government levels show some improvement, the majority still perceive them as weak, particularly at higher levels. There's a significant correlation between the government's political commitment and collaboration efforts, suggesting the need for stronger alignment.

Respondents express dissatisfaction with existing policies regarding pharmaceutical production and internationalization due to inadequate implementation and lack of supportive documents. This discourages local industries from pursuing international markets, leading to multiple challenges in the process.

Using the logistic regression model of analysis for the data gathered from MRs, the likelihood of having strong collaboration and coordinated efforts among the highest and medium levels of the government has significant effect at 88.2% and 99.6% on the internationalization of locally manufactured pharmaceutical products. Moreover, both the adequate government support for local production of pharmaceutical products and the political will in stimulating local production of pharmaceutical products have also significant effect on the dependent variable i.e., on the internationalization of locally manufactured pharmaceutical products at 99.6%.

Table 3. Logistic Regression result on the political commitment and collaboration of the government at different levels.

Collaboration, coordination, support of government in view of political will and commitment						
	B	S.E.	Wald	Df	Sig.	Exp(B)
political commitment at the highest level	.242	1.624	.022	1	.882	1.274
collaboration and coordinated efforts among the highest government level	-.242	1.624	.022	1	.882	.785
collaboration and coordinated efforts among the Medium government level	-50.650	9440.329	.000	1	.996	.000
Step 1 ^a collaboration and coordinated efforts among the lower government level	100.713	19291.341	.000	1	.996	5.485E+043
adequate government support for local production of pharmaceutical products	-66.381	12276.004	.000	1	.996	.000
political will in stimulating local production of pharmaceutical products	-33.070	6138.002	.000	1	.996	.000
Constant	133.194	25078.560	.000	1	.996	7.002E+057

3.6. The Adequacy of Government Support for Local Production of Pharmaceuticals and Related Commodities

Government initiatives, such as the Growth and Transformation Plan II (GTP-II) and the National Strategy and Plan of Action for the Development of Pharmaceutical Manufacturing in Ethiopia (NSPA-Pharma), aim to strengthen local pharmaceutical production. However, limited progress has been observed despite policy redesigns over the past 15 years.

Almost all Importers/Wholesalers, and retailer respondents

(IWRs) report inadequate government support for local pharmaceutical production. Additionally, a majority of respondents disagree with the notion of sufficient political will to stimulate local production.

Collaboration and coordination at different government levels correlate with support for local pharmaceutical production. Middle-level government coordination is associated with adequate support, while lower-level government efforts correlate with political will. Strong collaboration efforts among various government levels are positively correlated with both support and political will, though efforts at the highest level negatively correlate with political will.

Table 4. Cross tabulation results on political commitment and adequate support of the government.

Adequate government support for local production of Pharmaceuticals and related commodities	The political will in stimulating local production of pharmaceuticals and related commodities		
	Yes	No	Total
Yes	0	1	1
No	82	290	372
Total	82	291	373

The Political will in stimulating Local Production of Pharmaceuticals and Related Commodities.

Most (78.82%) of the IWRs concluded lastly that there is an absence of politics that will stimulate the production of pharmaceutical products and related commodities. Addition-

ally, employing a Pearson correlation on the data obtained from the IWRs, It is realized that the medium level of government has a negative correlation with the political will at 0.05 levels of significance.

3.7. Existence of Enabling Policies for and Their Benefits in the Internationalization of Pharmaceutical Products

The majority (58.33%) of manufacturing respondents perceive enabling policies in the country to promote local pharmaceutical production and retail, with approximately half (50%) benefiting from these policies. However, a notable proportion (41.67%) express not having benefited from them. In contrast, most Importers/Wholesalers, and Retailers Respondents (IWRs) (63.54%) believe there are no enabling policies for local pharmaceutical production and retail. Yet, a significant number (67.56%) agree that the govern-

ment prioritizes the pharmaceutical industry. Lack of enabling policies and low priority given to pharmaceutical industries significantly impact the internationalization of locally manufactured pharmaceutical products, as indicated by logistic regression analysis (policies: 38.5% significance level, industry priority: 23.7% significance level). While the majority of manufacturing respondents (70.83%) view pharmaceutical industries as government priority areas, a substantial minority (20.83%) hold differing views. Additionally, responses from Stakeholders and Partner Respondents (SPRs) reveal divergent opinions on the effectiveness of existing policies in promoting local pharmaceutical products.

Table 5. Logistic Regression results on policies and benefits from policies.

Variables in the Equation		B	S.E.	Wald	Df	Sig.	Exp(B)
	there are enabling policies to promote local production of pharmaceutical products and related commodities	-1.059	1.218	.756	1	.385	.347
Step 1 ^a	benefited from existing policies	.437	1.271	.118	1	.731	1.548
	pharmaceutical industries are among the top priority area	-1.076	.909	1.399	1	.237	.341
	Constant	4.708	2.362	3.975	1	.046	110.885

a. Variable(s) entered on step 1: Do you think that there are enabling policies to promote local production, Have you ever benefited from these policies, Do you think that pharmaceutical industries are among the top priority area.

3.8. The Emphasis Given for the Internationalization of Pharmaceutical and Related Products

From those 17 respondents of the manufacturing firms who have said that pharmaceutical industries are the top priorities of the government, 8 of them have benefited from the existing pharmaceutical policies. From the 24 respondents, 10 of them have said that existing policies enable to promotion of the local production of pharmaceutical products and the government has focus and gives priority to the industry.

3.8.1. Issues Related to Taxation

To either retain current investments or attract new ones, the costs of doing business must be low. One way of doing so is to weaken labor and environmental standards. The result is a "race to the bottom" as political jurisdictions compete with one another by progressively reducing the protec-

tions they provide to their citizens [17].

According to KII respondents, imported medical supplies, including medicines, face a uniform customs duty despite higher tariffs on locally produced inputs and raw materials, leading to inconsistency in application. The primary reason cited for this is the significant disparity in customs duty between locally produced goods (potentially up to 35% for items like bottles, vials, foils, primary packaging materials, etc.) and imported finished formulations, which typically incur only a 5% customs duty.

Utilizing a binary logistic regression model, it was found that receiving priority clearance services and the absence of a standardized customs procedure have a minor but statistically significant impact on the internationalization of locally manufactured pharmaceutical products.

Out of the respondents surveyed, 319 (52.52%) expressed dissatisfaction with the clearance services, highlighting their disorganization and the inconsistent customs procedures.

Table 6. Binary logistic regression result on getting clearance and clear custom procedures.

Does your company get priority clearance service	Is there uniform and clear custom procedure	Total
Yes	54	54
No	319	319
Total	373	373

3.8.2. Regulatory Related Challenges

Among pharmaceutical product producer (33.33%) confirm their companies possess local EFDA CGMP, indicating compliance with local regulations. However, a majority of respondents report their companies lack this certification. A small percentage (25%) of Stakeholder and Partner Respondents (SPRs) note their companies have sent products for international markets, suggesting limited international market penetration among surveyed companies.

A significant majority (66.67%) of KII respondents are aware of multilateral and bilateral agreements Ethiopia has signed, emphasizing the country's engagement in regional and international trade agreements despite not being a member of the East Africa Community (EAC).

More than half (54.17%) of manufacturing respondents perceive policies within the sub-Saharan region and other African countries as ineffective and poorly harmonized, potentially hindering cross-border trade and internationalization efforts. The regulatory harmonization system in Ethiopia is deemed ineffective, with nearly three-quarters (72.9%) of respondents indicating its limitations on internationalizing products. Lack of internal capacity is cited by a quarter (25%) of respondents as a major constraint for local pharmaceutical industries to meet international standards, with an additional 16.7% ranking it as a significant challenge.

All Importers/Wholesalers, Retailers Respondents (IWRRs) agree on the inadequacy of regulatory harmonization within the region, while a majority (69.97%) highlight challenges in accessing foreign currency as a priority issue.

3.8.3. Financing or Funding

Among pharmaceutical product producers, 33.33% confirm their companies comply with local EFDA CGMP regulations. However, a majority of respondents report their companies lack this certification. Stakeholder and Partner Respondents (SPRs) note that only 25% of their companies have exported products to international markets. A significant majority (66.67%) of KII respondents are aware of Ethiopia's involvement in multilateral and bilateral trade agreements, despite not being an East Africa Community (EAC) member.

More than half (54.17%) of manufacturing respondents perceive policies within the sub-Saharan region and other African countries as ineffective, potentially impeding inter-

national trade efforts. Ethiopia's regulatory harmonization system is viewed as ineffective by nearly three-quarters (72.9%) of respondents. Internal capacity constraints are cited as a major challenge by 25% of respondents, with an additional 16.7% ranking it as significant.

All Importers/Wholesalers, Retailers Respondents (IWRRs) unanimously agree on the inadequacy of regional regulatory harmonization, with a majority (69.97%) highlighting challenges in accessing foreign currency.

3.8.4. Access to Basic Infrastructures

All IWRRs lack adequate, uninterrupted access to energy and water. Half of manufacturing respondents have water access in their production sites, while the other half do not. Previous studies in Ethiopia highlight the need to upgrade deprived infrastructure, including transportation, power, and telecommunication. Efforts in this direction are deemed crucial. [18].

All IWRR respondents and the majority (18=75%) of manufacturing respondents confirm the availability of sufficient and well-developed communication setups.

3.8.5. Market Size and Potential for Local Industries

Among the surveyed participants, 282 individuals disclosed possessing an ample local market scope for their merchandise, with a predominant majority (20=83.33%) of manufacturing entities corroborating this assertion. The responses from 334 participants, representing the category of Importers/Wholesalers and retailers (IWRRs), revealed a strong unanimity concerning the profitability potential within the pharmaceutical product market. Nevertheless, 228 respondents from this cohort observed the encroachment of imported finished goods into the market, posing a competitive challenge to domestically manufactured counterparts. Conversely, a notable contingent of manufacturing respondents contended that imported finished goods do not directly compete with domestically produced alternatives.

3.8.6. Skilled Human Capital

All respondents agreed on the scarcity of easily semi-trained manpower in their firms. Additionally, 267 respondents (71.58%) acknowledged the inadequacy of skilled manpower, both in quantity and quality, within their organizations. Most partner and stakeholder respondents (66.67%) also cited a lack of semi-skilled manpower. A significant portion of respondents (252 = 67.56%) noted the easy entry and exit of highly skilled expats. Meanwhile, all IWRRs (373) indicated a lack of free or subsidized training opportunities abroad. However, SPRs presented a different perspective, with the majority (91.67%) stating that the entry and exit of highly skilled expats is not as easy as perceived.

3.9. Prioritization of the Challenges of Local Pharmaceutical Products Marketers and Producers

Using the rating system of variables, the data were collected from respondents regarding the challenges faced by pharmaceutical industries during the production or marketing of their pharmaceutical products in the world. Lack of supportive policy implementation and low ability to influence government were major concerns, with half of respondents agreeing on their significance. Perception issues among stakeholders and the public, corruption in policy implementation, and supply chain interruptions were also highlighted. However, the lack of finance and foreign currency received less attention as limitations to internationalization.

Continued supply of locally produced medicines posed a significant challenge, while respondents expressed optimism about the potential for internationalizing locally made pharmaceuticals. Price competitiveness and packaging attractiveness were cited as areas needing improvement in marketing strategies. Almost one-fourth of respondents were uncertain about banning imported medicines in favor of local ones, but the majority agreed on the feasibility. Additionally, there were calls for government intervention, including imposing high taxes on competitive imports and establishing government-owned pharmaceutical industries.

3.10. Public Perception

3.10.1. Quality of Locally Produced Products

As per the MRs' feedback, the quality of locally produced medicines and related commodities compared to imported ones significantly influences the internationalization of local products, accounting for 77.4%. A large majority (83.33%) of respondents agreed that locally produced medicines and related commodities are of equal quality to imported ones, while a small proportion (16.67%) expressed uncertainty.

Among pharmaceutical product producers, 8 (33.33%) respondents confirmed that their companies adhere to local EFDA CGMP standards, while the majority reported that their companies do not comply. None of the manufacturing respondents have products registered outside of Ethiopia, whereas only a few (25%) of SPRs indicated that their company has exported some products to the international market. Furthermore, 13 (54.17%) of manufacturing respondents believe that policies within the sub-Saharan region and other African countries are not effectively harmonized and are not conducive to their operations.

3.10.2. Public Procurement

All respondents agreed on local protection for medicines, though IWRRs noted inconsistency. Despite Ethiopia's long pharmaceutical history, local products face mixed reception. While most IWRRs prefer local medicines, a minority opts

for imported ones.

KII respondents noted that customers in major cities tend to prefer imported products.

Regarding internationalization, most IWRRs believe it's lacking, citing reasons such as trust in foreign products and better packaging. The government aims to enhance local pharmaceutical capacity but faces challenges like finance and policy influence. IWRRs identified key factors hindering internationalization.

From IWRRs, 89.28% believed in the lack of internationalization of local products. Among them, various reasons were cited, including trust in foreign pharmaceutical companies, better packaging, and availability of imported goods. Lack of finance and supportive policies negatively affect industry capacity, while regulatory issues and corruption impede progress.

4. Discussions

Numerous studies draw attention upon the concept of internationalization of pharmaceutical industries acceleration of internationalization, the employment, economic and policy challenges faced by pharmaceutical industries, perceptions that affect pharmaceutical market access, the globalization of pharmaceutical industry while the unmet need of and the related broader challenges for internationalization of pharmaceutical products of manufacturers in developing countries like Ethiopia is not yet investigated; However, little is known about the challenges of internalization of African Pharmaceuticals [4].

This section of the dissertation thereon stipulated the results which are found as the out puts from conducting the study based on formerly stated objectives in section one of this document. The results are explained here based on the methodology and the objectives of the study employing both quantitative and qualitative data analysis methods. Relevant theories and results of former empirical studies are incorporated in both the result and discussion sub-sections of the dissertation for triangulation purposes beyond the triangulation of gathered and analyzed descriptive data using qualitative data.

In today's globalized world, businesses strive to expand beyond local boundaries, yet products from developing countries often face hurdles to acceptance. These challenges stem from a lack of supportive policies and government commitment, hindering local industries from fully internationalizing their pharmaceutical offerings. Despite the importance of political commitment, especially at the highest government levels, respondents note a dearth of support in Ethiopia, impeding both local production and international recognition of pharmaceuticals. This lack of governmental backing has led to restricted access to both local and international markets, impacting product quality and efficacy.

Statistical analysis underscores the critical role of government collaboration and support levels in driving the in-

ternationalization of local pharmaceuticals. Adequate government backing and political will are significant factors influencing this process, particularly at the middle and highest government tiers. However, there's a noted lack of coordination and collaboration efforts at these levels, with respondents highlighting weak governmental support and limited political commitment.

The logistic regression model analysis showed that the likelihood of having strong collaboration and coordinated efforts among the highest and medium levels of the government has significant effect at 88.2% and 99.6% respectively on the internationalization of locally manufactured pharmaceutical products.

Policies governing pharmaceutical production and promotion are inconsistent and inadequately implemented, further impeding industry growth. The absence of clear directives and guidelines exacerbates challenges faced by local industries seeking to internationalize their products. Despite these obstacles, locally produced medicines remain competitively priced, thanks in part to irregularities in custom duties, which are significantly higher for local inputs compared to finished imported formulations.

Respondents highlight the discrepancy in custom duties, with locally produced inputs subject to higher rates than imported finished products. Despite this, locally produced medicines remain relatively affordable, ensuring continued market viability. However, challenges persist in registering products outside Ethiopia, indicating further barriers to international expansion.

Even though Ethiopia isn't part of the East Africa Community (EAC), membership in this community offers significant advantages. Many respondents are aware of Ethiopia's participation in multilateral and bilateral agreements, as well as its founding membership in IGAD. IGAD membership provides opportunities for free trade and business expansion among member countries, fostering growth in local pharmaceutical industries. However, respondents perceive IGAD's effectiveness as lacking.

Regional harmonization efforts like the African Medicines Regulatory Harmonization (AMRH) initiative aim to streamline market authorization processes and align legislative frameworks. Despite these efforts, respondents unanimously criticize the ineffective implementation of regulatory harmonization within and across regions. The scarcity of foreign currency exacerbates challenges in accessing raw materials, hindering pharmaceutical production.

Weak regulatory linkages and sector-wise collaborations significantly impact export performance and local market supply of pharmaceuticals. Decision-making processes are hindered by skepticism and lack of cooperation among stakeholders. Furthermore, there's a lack of binding agreements and laws guiding the promotion and internationalization of locally produced pharmaceuticals, contributing to their limited global reach.

Challenges facing Ethiopian pharmaceutical industries in-

clude the inability to influence government policies, corruption, and negative perceptions of local products. Internal capacity limitations, infrastructure deficiencies, and regulatory hurdles further hinder internationalization efforts. Despite access to the local market, entry into international markets remains challenging. However, the pharmaceutical industry does benefit from access to semi-skilled manpower, albeit with limitations in both quantity and quality.

The policy introduced in 2016/17 lacks effective implementation, leading to disbelief and limited support from stakeholders and the public regarding the internationalization of locally produced pharmaceuticals. The absence of clear directives and guidelines hampers efforts to navigate procedural and implementation protocols for internationalization. This lack of supportive policy implementation discourages local industries and exacerbates challenges in their efforts to expand internationally.

Policy manipulation and corruption during implementation further undermine support for local industries, fostering a perception that they lack the capacity to produce quality products. Despite preferences among medicine prescribers for local medicines, stakeholders and the public maintain doubts about the industry's capabilities.

Challenges persist at both the national regulatory and regional harmonization levels, hindering the marketing and authorization of medical products and the alignment of legislative frameworks. Respondents highlight inadequate regulatory harmonization and corrupted policy implementations, exacerbating challenges for companies seeking to internationalize their products. The impracticality of the regulatory harmonization system further impedes internationalization efforts.

The study reveals significant financial distress among Ethiopia's local pharmaceutical industries, affecting their international market entry and routine operations. Respondents from manufacturing firms identified lack of finance, foreign currency, and credits as primary challenges, with 91.7% citing this issue. Additionally, 70.8% noted the lack of finance and credits as significant hindrances, while 66.7% highlighted the industries' inability to influence government policies regarding internationalization.

In case of Ethiopia, the internationalization of pharmaceutical products is almost none [4] and the bad support of electricity is a challenge for foreign investors in Ethiopia's manufacturing industry where Blackouts in the rainy season can stop the manufacturing line and raise the overall costs. Further, telecommunication is on a high cost level. Basically transportation is also one of major problems since Ethiopian Shipping Lines as well as Ethiopian Air Lines are costly and not accessible to different regions [19].

In Ethiopia, the internationalization of pharmaceutical products is minimal, exacerbated by inadequate support infrastructure. Electricity shortages, especially during the rainy season, disrupt manufacturing operations and increase costs. Additionally, high telecommunications expenses and costly

transportation, including limited access to Ethiopian Shipping Lines and Ethiopian Air Lines, pose significant challenges [19]. These issues as barriers to the internationalization of Ethiopian pharmaceutical products, the high cost of production was not a significant concern in this study [18].

There are several challenges facing Ethiopian pharmaceutical industries in their efforts to expand internationally. These include a lack of internal capacity to meet global standards, inadequate government support policies, and the industries' limited influence on government decisions regarding internationalization. Additionally, there's a widespread belief among stakeholders and the public that local industries lack the capability to compete globally, leading to reduced support. Corruption in policy implementation tends to favor imported products, exacerbating the challenges faced by local industries. Financial constraints, negative international perceptions of Ethiopian pharmaceuticals, infrastructure deficiencies, regulatory inconsistencies, and high production costs further hinder international commercialization efforts in the sector.

Furthermore, the current policy implementations have reinforced the perception among stakeholders and the public that locally produced pharmaceuticals lack quality and cannot be effectively internationalized. This perception diminishes support for the industry in this regard. Key informant interview (KII) respondents emphasized the vital role of the pharmaceutical industry in economic development. They highlighted its contribution to job creation, technology transfer, cost reduction through import substitution, and the lessening of foreign currency and medical supply demand. These factors contribute to self-sufficiency and the provision of affordable, high-quality products, particularly benefiting impoverished citizens in developing nations. Additionally, the industry plays a significant role in global market expansion, contributing to sustainable globalization efforts.

Respondents noted that both local and international stakeholders perceive the local pharmaceutical industry's capacity to produce quality products as inadequate, hindering internationalization. There's also a lack of mutual awareness among stakeholders regarding the importance of promoting local products globally, despite high acceptance locally. The absence of binding agreements and laws to guide the promotion and internationalization of locally produced pharmaceuticals results in limited attention and support for the industry.

Owners of manufacturing firms and professionals have limited influence against unimplemented policies. Collaborative efforts from the government and stakeholders are lacking to achieve the internationalization of local pharmaceutical products for global market access.

5. Conclusion and Recommendations

The empirical analysis conducted, and its findings show that there are multiple and interlinked challenges that hamper the internationalization of pharmaceutical products. These challenges impact the local production as well as the marketing

performances of importers, wholesalers, and retailers of pharmaceutical products in Ethiopia which emanate from the internal and external environment of the pharmaceutical industries. Though the degree of the impacts of the challenges is at variance level from industry to industry, mainly the research has found lack of capacity and opportunities to access international markets based on the concept globalization, lack of government support, fragile and corrupted local policy implementation, frail local, regional and sub-regional collaboration, coordination and harmonization of policies, difficulties to get relevant resource like finance and human resources and country of origin as a barrier as the main challenges for local industries to internationalize their locally produced products.

Among the principles of globalization, countries from any part of the world reached to consensus to invest their resources worldwide through FDI, to promote knowledge and skill transfers, to share resources, to support developing countries through SDG for the effect on their GDP or other economic development endeavors. However, the existing practice from the research showed that the collaboration of international and regional countries is found to be too contemptible. Moreover, locally produced products are not accepted by most international countries, especially in developed worlds. Not only this, there are partisan perceptions impeded in the local and international communities in labeling the products with country of origin. All the way through, pharmaceutical industries from those developing countries are unable to promote their products and access international markets because of their poor economic position.

Regarding the support from the local, regional, and sub-regional governments, the study pinpointed that the collaborative and coordinated efforts by the local, regional, and sub-regional governments including the regulatory bodies are found underprivileged to get the desired results as expected.

There are workable policies on paper whereas these policies are left on tables without any signal of executions. Therefore, weak support from the local government in executing existing policies and providing support to the efforts on internationalizing locally produced products is found as a fundamental gap because nothing will happen without the harmonization of policies and the support of the government.

The existence of fragile and corrupted local policy implementation, frail local, regional, and sub-regional collaboration, coordination, and harmonization of policies together with the abandoned support of international, regional, sub-regional, and local governments and agencies have exacerbated the unintelligibility of the origins of the factors that deter the internationalization of pharmaceutical products produced by the local industries of the country.

In the face of all these facts, the products of the local pharmaceutical industries customarily confront challenges in accessing financial and trained human resources. This on the other hand limits the production and continuous supply of products to the market. Similarly, the shortfall and high cost of getting trained professionals from local and international

markets diminished the efforts of the industries to make their products registered and marketed internationally.

As inter-organizational challenges, there are clumsy efforts from pharmaceutical industries to establish international partnerships and to influence the local government, stakeholders, and regulatory bodies to get appropriate support and to urge them to put existing policies in action. Furthermore, the intimacy, coordination, and collaboration of work relationships among local trade unions, responsible government ministries, stakeholders, and partners also showed that there is less support and emphasis is given for the internationalization of the products.

6. Recommendations

The production, promotion, and internationalization of pharmaceutical products in the developing world are crucial for improving human health and reducing mortality rates. Furthermore, their recognition significantly contributes to economic growth and development by fostering healthier, more productive citizens and reducing dependency on imported products, thus preventing excessive foreign currency expenditure. To do so and the like, the researcher proposes the following recommendation for international, regional, sub-regional, and local stakeholders who have direct involvement in the improvement of the gaps identified and the realization of the internationalization of locally produced pharmaceutical products of Ethiopia, under the findings of the study.

The international community and stakeholders abroad should support developing countries by providing technical skills and strategic advice, promoting globalization through knowledge and technology transfer, including FDI, with the WHO prioritizing industry empowerment.

International pharmaceutical companies, particularly those from developed nations, should seek partnerships or direct investments in developing countries to leverage surplus resources, thereby reducing production costs and advancing globalization efforts and Sustainable Development Goals (SDGs) uniformly.

Policy advocacy and promotion by existing pharmaceutical stakeholders should be in place through professional associations and unions must to influence the government for stronger partnerships to internationalize locally produced pharmaceutical and medical items.

Abbreviations

AGOA	Africa Growth and Opportunity Act
AOE	African Economic Outlook
AU	African Union
CSO	Community Service Officer
EBA	Everything But Arms
EFDA	Ethiopian Food and Drug Administration
EME	Early Market Engagement

FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
IGAD	Intergovernmental Authority for Development in East Africa
IMF	International Monetary Fund
ISO	International Standard Organization
IWRs	Importer, Wholesaler and Retailer Respondents
MNEs	Multinational Enterprises
MRs	Manufacturer Respondents
OECD	Organization for Economic Cooperation and Development
OFDI	Outward Foreign Direct Investment
SA	Strongly Agree
SD	Strongly Disagree
SDGs	Sustainable Development Goals
SPRs	Stakeholder and Partner Respondents
UNECE	United Nations Economic Commission for Europe
WTO	World Trade Organization

Author Contributions

Guyassa Daniel Waktole: Conceptualization, Data curation, Investigation, Project administration, Resources, Supervision, Validation, Writing – original draft

Tefera Tezera Negera: Data curation, Formal Analysis, Methodology, Software, Validation, Visualization, Writing – review & editing

Conflicts of Interest

The authors declare no conflicts of interest.

References

- [1] MOTI. Ethiopia Trade and Transformation Synthesis DIAGNOSTIC TRADE INTEGRATION STUDY, 2019 July; 2.
- [2] Mwangi JM. Towards African Medicines Regulatory Harmonization: The case of the East African Community. *Pharmaceuticals Policy and Law*, 2018; 18(1–4): 91–98. <https://doi.org/10.3233/PPL-160435>
- [3] Banda G, Wangwe S, and Macintosh, M. *The Pharmaceutical Industry in Africa*, 2016.
- [4] Muhia J, Waithera L, and Songole, R. Factors Affecting the Procurement of Pharmaceutical Drugs: A Case Study of Narok County Referral Hospital, Kenya. *Medical & Clinical Reviews*, 2017; 03(04). <https://doi.org/10.21767/2471-299x.1000061>
- [5] Bonaglia, F and Mathews, J. *Accelerated Internationalization by Emerging Multinationals: The Case of White Goods*, 2016.
- [6] Wiedersheim-Paul J. *Theoretical Foundations of Firm Internationalization*, 2019, 23–24.

- [7] Ncube BM, Dube A, and Ward K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. *J Pharm Policy Pract* 2021, 14(1): 1–12. <https://doi.org/10.1186/s40545-020-00281-9>
- [8] Vieira J, Frade R, Ascenso R, Martinho F, and Martinho D (2021) Determinants of internationalization as levers for sustainability: A study of the Portuguese pharmaceutical sector. *Sustainability*, Switzerland, 2021, 13(17): 1-9. <https://doi.org/10.3390/su13179792>
- [9] Ngamu E. Challenges facing marketing of pharmaceutical products in Kenya, 2016.
- [10] Kassahun TE. ETHIOPIA AN EMERGING MANUFACTURING HUB IN AFRICA. Addis Ababa, 2018.
- [11] Robertson, R. Effects of regulating international trade on firms and workers. *IZA World of Labor*, 2020 June. <https://doi.org/10.15185/izawol.439>
- [12] Gabel M. Globalization and its impact on environmental management. *Environmental Quality Management*, 2021, 6(3): 89–93. <https://doi.org/10.1002/tqem.3310060312>
- [13] Brief, P. Policy Brief: Addressing the Challenges of Local Pharmaceutical Production in Ethiopia, 2021.
- [14] Boche B, Mulugeta T, and Gudeta T. Procurement Practice of Program Drugs and Its Challenges at the Ethiopian Pharmaceuticals Supply Agency: A Mixed Methods Study. *Inquiry*, United States 2022; 59. <https://doi.org/10.1177/00469580221078514>
- [15] Taole N. Evaluation of the INNOPAC Library System in selected consortia and libraries in the Southern African Region: implications for the Lesotho Library Consortium, 2008.
- [16] Vogel D and Kagan RA. Dynamics of Regulatory Change: How Globalization Affects National Regulatory Policies An Introduction, 2021.
- [17] Factors Affecting Foreign Direct Investment in Ethiopia: ARDL Approach to Co-integration. *European Journal of Business and Management*, 2020. <https://doi.org/10.7176/ejbm/12-35-02>
- [18] TAYE, L. Assessment of External factors for Internalization of a pharma, 2019.
- [19] Marew et al. Trends and Challenges in Access to Essential Medicines in Ethiopia and the Contributions of Local Pharmaceutical Production. *Ethiop J Health SciI*, 2022, 32(5): 1027–1042.