# LEGAL ANALYSIS ON ATTRACTING FOREIGN INVESTMENTS FOR PHARMACEUTICAL INDUSTRIES IN EAST AFRICA

## CASE STUDY OF RWANDA

**By**

**JYAMBERE Diane**

**THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE MASTER'S DEGREE IN INTERNATIONAL AND ECONOMIC AND BUSINESS LAW.**

**Supervisor**: **Dr. Mbonigaba Callixte**

**KIGALI INDEPENDENT UNIVERSITY ULK**

**Kigali, September 2023**

# DECLARATION

I**,** JYAMBERE Diane declare that the work presented in this thesis is original. It has never been presented to any university or Institution. Where people's works have been used, references have been provided, and some cases, quotations made. In this regard, I declare that this work is originally mine.

**Signature …….**

**Date …. /…/ 2023**

# APPROVAL

I, Dr MBONIGABA Callixte, hereby declare that this thesis entitled **"Legal Analysis on attracting Foreign Investments for Pharmaceutical Industries in East Africa: Case Study of Rwanda"** was conducted by JYAMBERE Diane under my guidance and supervision.

.

**Supervisor:** Dr MBONIGABA Callixte

**Signature: ……**

Date: …. /……/ 2023

# DEDICATION

To the Almighty God;

To our Parents;

To our brothers and Sisters;

To all my Friends and Colleagues

## ACKNOWLEDGEMENTS

The Completion of this work should not have been easy without the material and moral support, Cooperation, Kindness and guidance of a number of people who deserve special thanks, especially the Founder and President of ULK, Professor Dr. RWIGAMBA Balinda and ULK Masters of International Economic and Business Law for having tersely looked for suitable lecturers from all corners of the globe that would suit the needs of this competitive world. With a feeling of satisfaction, I thank my supervisor Dr MBONIGABA Callixte for his valuable help during my research, his advices both in correcting mistakes from language and topic research orientation, critics towards me, all these have contributed for this work's quality.

Hence it is result of exclusively personal efforts. Therefore, I thank God for his protection upon me, because I am still alive. My appreciation also goes to my brothers and sisters for their love and encouragement throughout my life and moral support that have contributed to the success of my education.

Finally, I thank also all ULK staff particularly to the all lecturers of the school of law who helped me in stepping forward throughout my academic progress till the end, my classmates whose support in one way or another made my academic progress and this work successfully.

May God bless you all!

JYAMBERE Diane

## LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ACTS | : African Centre for Technology Studies |
| ADR | : Adverse Drug Reaction |
| AMA | : African Medicines Agency |
| AMRH | : African Medicines Regulatory Harmonization |
| API | : Active Pharmaceutical Ingredients (APIs) |
| Art | : Article |
| AU | : African Union |
| BE | : Bioequivalence |
| C.L.R | : Codes et Lois du Rwanda |
| CAPAs | : Corrective Actions and Preventive Actions |
| CCB | : Civil Code Book |
| COMES | : Common Market for Eastern and Southern Africa |
| CROs | : Contract Research Organizations |
| CRP | : Collaborative Registration Procedure |
| CTD | : Common Technical Document |
| E.G | : For Example |
| E.G | : For example |
| EAC | : East African Community |
| EAC | : East African Community |
| Ed | : Edition |
| EDPRS | : Economic Development and Poverty Reduction Strategy |
| EM | : Essential Medicines |
| Etc | : et caetera (and ends) |
| FDA | : Food and Drugs Authority |
| FDI | : Foreign Direct Investment |
| FRW | : Rwandan Franc |
| GBT | :Global Benchmarking Tool |

GDP : Gross Domestic Product

GHP : Good Hygienic Practices

GLP : Good Laboratory Practices

GMP : Good Manufacturing Practice

GMP : Good Manufacturing Practices

GSP : Good Storage Practices

HSSP : Health Sector Strategic Plan

Http : Hypertext transfer protocol

i.e: Id est (That is)

Ibid : Ibidem (Same book, same author, same page)

ICSID : International Centre for the Settlement of Investment Disputes

Idem : Same book, same author, different pages

IPA : Investment promotion agency

IPAS : Investment promotion Agency as policy

ISO : International Organization for Standardization

ITO : The International Trade Organization

IVP : Veterinary Immunological Products

JV : Joint Venture

KIIs : Key Informants Interviews

KNBS : Kenya National Bureau of Statistics

LAPD : Los Angeles Police Department

LIMS : Laboratory Information Management System

LMICs : Low-Middle Income Countries

LPPs : Local Pharmaceutical Producers

M&E : Monitoring and Evaluation

MA : Marketing Authorization

MIGA : Multilateral Investment Guarantee Agency

MoH : Ministry of Health

MTaPS : Medicines, Technologies, and Pharmaceutical Services program

NCDs : Non-Communicable Diseases

NCST : National Council for Science and Technology

No : Number

NPP : National Pharmacy Policy

NST : National Strategy for Transformation

NUR : National University of Rwanda

O G : Official Gazette

O.G.R.R : Official Gazette of the Republic of Rwanda

OECD : Organization for Economic Co-operation and Development

OIE : World Organization for Animal Health

OPIC :Overseas Private Investment Corporation

P. : Page

Par : Paragraph

Parag : Paragraph

PIC/S : Pharmaceutical Inspection Co-operation Scheme

PIRS : Performance Indicator Reference Sheets

PMPA : Pharmaceutical Manufacturing Plan of Action

PMS : Post-Marketing Surveillance

PPB : Pharmacy and Poisons Board

PPP : Public private partnership

PRIMS : Pharmaceutical Regulatory Information Management System

PSDS : Private sector Development policy and strategy

PV : Pharmacovigilance

QMS : Quality Management System

RAB : Rwanda Agriculture Board

RARDA : Rwanda Animal Resources Development Authority

RMS : Rwanda Medical Stores

RSB : Rwanda Standards Board

SADC : Southern African Development Community

| | |
|---|---|
| SC | **:** Supreme Court |
| SGCI | : Science Granting Councils Initiative |
| SMART | : Specific, Measurable, Achievable, Realistic, and Time-bound |
| SME | : Small and Medium Enterprise |
| SOP | : Standard Operating Procedure |
| SPA-PHI | : Global Strategy and Plan of Action on Public Health, Innovation and Intellectual |
| Supra | : Same Author, after interruption of other authors |
| SWOT | : Strengths, Weaknesses, Opportunities, and Threats |
| T | : Tome |
| TNCs | : transnational corporations |
| TRIMS | : Trade Related Investment Measures |
| UDHR | : Universal Declaration of Human Rights |
| ULK | : University Libre de Kigali (Kigali Independent University) |
| UN | : United Nations |
| UNCTAD | : United Nations Conference on Trade and Development |
| UNCTE | : United Nation Conference on Trade and Employment |
| UNIDO | : United Nations International Development Organization |
| UR | : University of Rwanda |
| UR-CST | : University of Rwanda, College of Science and Technology |
| USAID | : United States Agency for International Development |
| Vol | : Volume |
| VS | : Versus |
| WTO | : World Trade Organization |
| WTO | : World Trade Organization |
| WWW | : World Wide Web |
| ZPA | : Zanzibar investment promotion Agency |

**TABLE OF CONTENTS**

# CHAPTER ONE: GENERAL INTRODUCTION

## 1.1. BACKGROUND

Throughout the world the international investment, economic integration and globalization are being done. And it is in this sense that East Africa has established laws, rules, regulations and Policies with several purposes of attracting foreign investment for pharmaceutical industries[1].

Therefore, in terms of international investment; attraction, promotion and protection are worth noting that it is necessary condition for the development of the international investment. It is so essential for the progress of underdeveloped and developing countries especially in Rwanda, and for the continuing prosperity of more East African Countries[2].

Besides, that attraction and other substantial condition of development of the international investment is security of property invested in foreign pharmaceutical industries against such non-commercial risks as discrimination, confiscation or unfair compensation as well facilitating foreigners to practice their pharmaceutical industries in East Africa Community[3].

And it is worth noting that this prudent standard for attracting foreign investments on the pharmaceutical industries investment in East African Community is for guaranteed pharmaceutical industries investors and is also complementary with the 2nd EAC regional pharmaceutical manufacturing plan of action 2017–2027, Kenya's Health Policy Framework (1994) and clinical officers (Training, Registration and Licensing) Act (1988), Tanzania sustainable industries development policy (1996–2020), Tanzania Integrated Industrial Development Strategy (2025), EAC Health .

[1] DUNNING, John (1984), "Changes in the level and structure of international production: The last one hundred years", in M. Casson (ed.), The Growth of International Buisiness (London: Allen and Unwin).
[2] KENWOOD, A.G. and A.L. LOUGHEED (1994), The Growth of the International Economy, 1829-1990, third edition (London: Routledge)
[3] National Institute of Statistics (NIS) [Rwanda], Ministry of Health (MOH) [Rwanda] and Macro International Inc. (2008). Rwanda Service Provision Assessment Survey (2007). Calverton, MD, USA: NIS, MOH and Macro International Inc.

Sector Strategic Plan: 2015–2020. The Rwandan law nº 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, law n° 74/2013 of 11/09/2013 establishing Rwanda food and medicines authority and determining its mission, organization and functioning. The law nº 013/2019 of 30/06/2019 governing Rwanda Biomedical Centre, law nº 45/2012 of 14/01/2013 on organization, functioning and competence of the council of pharmacists, Health Sector Research Policy of February 2012 and others which are elaborated to attract and facilitate foreign pharmaceutical industries investors to come flow them and help developing countries in regards of foreign pharmaceutical industries[4].

It is paramount noting that in order to guarantee an investment in pharmaceutical industries; Rwanda must satisfy itself fair, equitable treatment and legal attraction for foreign investors who want to invest in pharmaceutical industries. The 1948 Havana charter for an international trade organization provides that foreign investments should be assured "just and equitable treatment.[5]

The production of the Rwandan Private Health Services Packages is the first description of health care service packages for the private sector in Rwanda. It demonstrates an effort to facilitate partnerships between public and private health care providers to strengthen the healthcare structure and services provided[6], was completed through a series of workshops and stakeholder feedback activities. The Ministry of Health worked with all the participants (public and private health care providers) for their contribution to this effort. It was supported in this process by the Rwandan Health Systems Strengthening Activity (RHSSA), a USAID.

---

[4] law nº 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, law n° 74/2013 of 11/09/2013 establishing Rwanda food and medicines authority and determining its mission, organization and functioning, law nº 013/2019 of 30/06/2019 governing Rwanda Biomedical Centre, **lawº 013 BIS /2019 of 30/06/2019** modifying Law no 11/2017 of 06/04/2017 establishing Rwanda Law Enforcement Specialized Academy and determining its mission, powers, organization and functioning, law nº 45/2012 of 14/01/2013 on organisation, functioning and competence of the Council of Pharmacists, Health Sector Research Policy of February 2012

[5] Article 11 point 2 Al.2 ,of the UNCTE held at havana, cuba from november 21, 1947, TO MARCH 24, 1948

[6] Rwandan Private Healthcare Service Packages, retrieved on https://e-huriro.rcsprwanda.org/wp content/uploads/2023/05/Private_Health__Facilities_service_packages__in_Rwanda.pdf accessed on 23rd September 2023.

funded project managed by Management Sciences for Health[7]. This was strengthening its relationship with the private sector. This collaboration is based on

1) Greater participation of the private sector in the provision of healthcare services,

2) Improved access to care using services offered by the private sector and

3) Strengthening the capacity of a unit within the MoH that oversees the private health sector. Private healthcare facilities are owned and operated by physicians, nurses, and other allied healthcare providers[8].

Some of these facilities provide hospitalization and some provide a variety of specialty services such as obstetrics and gynecology, pediatrics, ophthalmology, dental, physiotherapy, mental health and laboratory investigations. Most of these services currently reside in Kigali[9].

Questions rose by the study on: "**Legal Analysis on attracting Foreign Investments for Pharmaceutical Industries in East Africa: A Case study in Rwanda.**

The reason underlying the choice of this study is attracting foreign investment for pharmaceutical industries in East Africa comparison between Kenya and Rwanda in order to progress of this domestic economic development and continuing prosperity of foreign investment through analyzing how the international, regional and domestic laws related to the foreign investment for pharmaceutical industries are being legally facilitated within East Africa especially in Rwanda by comparing with Kenya[10].

[7] WHO. Integrated Management of Childhood Illness: Chart Booklet. March 2014. World Health Organization: Geneva
[8] Ministerial Order No 14/02 Min 98 of March 26, 1998. Defining the Functioning Norms of Private Health Establishments in Rwanda.
[9] M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 104-21
[10] The Market Dynamics of Generic Medicines in the Private Sector of 19 Low- and Middle-Income Countries between 2001 and 2011- A Descriptive Time Series Analysis Warren A. Kaplan, Veronika J. Wirtz, Peter Stephens 2013, p16-20

## 1.2. PROBLEM STATEMENT

The inadequate supply of essential medicines is one of the main challenges faced by Rwanda. To address this challenge, it is crucial to build and strengthen the capacity of pharmaceutical industries in Rwanda. This requires allowing such state to get affordable, efficacious, high-quality and safe pharmaceutical products within its territory, region and international level which can significantly contribute to simultaneous achievement of public health and industrial development objectives.[11].

Rwanda has put in place legislations to attract foreign investment. Law n° 006/2021 of 05/02/2021 on investment promotion and facilitation grants incentives to investors carrying out businesses in various sectors, including tourism, manufacturing, exports, mining, water, electricity, etc. Nevertheless, that law grants no incentives to pharmaceutical industries. This seems a challenge as pharmaceutical industries are very important for the life of Rwandan people as their promotion would improve directly their living conditions.

Accordingly, this research aims at answering the following questions.

### 1.3. Research Questions

1. To what extent Rwandan investment law attract foreign investment for pharmaceutical industries?
2. What are mechanisms that should be undertaken in Rwandan investment law to ensure the effective attraction of the foreign investors for pharmaceutical industries in Rwanda?

[11] Keko Pharmaceutical Industries Limited, (1997), Dar-es-Salaam 43-51 p, Tanzania National Commercial Directory – NCD, retrieved on https://ncd.co.tz/listing/keko-pharmaceutical-industries-1997-ltd accessed on 23rd september , 2023.

## I.4. HYPOTHESES

In response to the above questions, the following hypotheses may be useful:

The Rwandan investment law should provide the policies and incentives laws that attract the foreign investment in Pharmaceutical Industries.

The Rwandan legal systems should protect the foreign properties for pharmaceutical industries invested in Rwanda against non-commercial risks as discrimination, confiscation or unfair compensation and be effective at reducing pharmaceutical products come from outside.

## I.5. OBJECTIVES OF STUDY

This research has the following objectives:

Setting out the relevant foreign investment for pharmaceutical industries opportunities available in Rwanda.

Encourage the Partner States to facilitate and the incentives for foreign investors in pharmaceutical industries.

Making the Rwandan investment law attractive to the foreign investors for setting up pharmaceutical industries in Rwanda.

Mobilizing the foreign investors to invest their capital for pharmaceutical industries in Rwanda.

## I.6. RESEARCH METHODOLOGY

In order to achieve our objectives, we have used different technique and methods. Therefore, only systematic intensive investigation into, or inquiry of, fact qualifies to get the label of research. And it becomes systematic when a researcher, in his quest for knowledge and pursuit of truth, attempts to collect the required information from various sources and in a variety of ways systematically and exposes data to a severe and intensive scrutiny. Research, thus, involves systematic scientific investigation of facts or their hidden or unknown facets with a

view to determining or ascertaining something, which may satisfy the curiosity of the investigator and carry forward his knowledge[12].

### I.6.1. TECHNIQUE

One technique has been used thought our research is the documentation technique.

### I.6.2. DOCUMENTATION TECHNIQUE

The documentation technique has been useful especially in collecting data available in books, treaties, reviews, case laws, investment reports and internet.

### 1.6.3. THE METHODS

In my research, the following methods have been particularly useful:

### I.6.4. COMPARATIVE METHOD

Comparative legal research is a systematic exposition of rules, institutions, and procedures or their application prevalent in one or more legal systems or their sub-systems with a comparative evaluation after an objective estimation of their similarities and differences and their implications. I have chosen Kenya, for its system used have become successfully attracted foreign investors especially in pharmaceutical industries.

### I.6.5. ANALYTICAL METHOD

This method has enabled me to make the systematic analysis of information and data collected relating to legal protection and promotion of foreign investment within East African Community.

[12] D Slesinger and M Stephenson, The Encyclopedia of Social Sciences, vol IX (MacMillan, 1930) 78 p

### I.6.6. SYNTHETICAL METHOD

This method has helped us to synthesize the collected data in a very clear and concise document.

## I.7. SCOPE OF THE STUDY

This study is conducted within the broad field of international investment law and slight look to international Economic and business law.

Though the study focuses at the Rwanda experience, it will have, where needed, a look to some foreign legal practices related to foreign investment attraction, promotion and protection for pharmaceutical Industries.

Furthermore, this study analyzes cases, events and innovations which occurred from the establishment of Rwandan laws, rules, regulations and Policies that helps attraction, protection and promotion to the foreign investment for pharmaceutical industries up to 2023.

It is limited in time, space and domain, in part of time, because it is particularly kept attention and was laid from 2013, where the Law n$^{o}$ 47/2012 of 14/01/2013 relating to the Regulation and inspection of food and pharmaceutical products and Law n° 006/2021 of 05/02/2021 on Investment promotion and facilitation. It is in space, it has been under African, especially in Rwandan law which means it is Continental but with specialty in Rwandan territory. It in Domain, because the subject of this work falls into International Economic and Business law.

## I.8. STRUCTURE OF THE STUDY

With abstraction to the general introduction and the conclusion, this work is composed of five chapters

Chapter one is related to the general introduction, chapter two is related to conceptual and theoretical framework. Chapter three deals with Investment promotion and facilitation under Kenyan law, chapter Four deals with the attraction foreign investments for pharmaceutical industries under Rwandan law. Finally, this work will be ended with chapter five which is general conclusion and recommendation.

# CHAPTER II: CONCEPTUL AND THEORETICAL FRMEWORK

Throughout this chapter, some key concepts will be defined and some general knowledge about the topic will be shared.

## 2. DEFINITION AND NOTION OF KEY CONCEPTS

The following terms will be defined: EAC, Investment, Direct Investment, Foreign Investment, Portfolio Investment, international investment, Incentive, bilateral investment treaty, multilateral investment treaty.

### 2.1. Foreign

It is beyond the boundaries of one's country in or to a foreign country traveling abroad. Foreign company a company incorporated outside Rwanda but which is carrying on business in Rwanda; A foreign corporation is a corporation which is incorporated or registered under the laws of one state or foreign country and does business in another. In comparison, a domestic corporation is a corporation which is incorporated in the state it is doing business[13]. The nature of the corporation (foreign or domestic) will impact several aspects of the corporation's organization, such as the requirement to be registered as a foreign corporation in the place of business: a foreign corporation must file a notice of doing business in any state in which it does substantial business[14].

### Foreign Investments

Foreign investment refers to the investment in domestic companies and assets of another country by a foreign investor. Large multinational corporations will seek new opportunities for economic growth by opening branches and expanding their investments in other countries.

[13] UNCTAD (2011b). Foreign Direct Investment in LDCs: Lessons Learned from the Decade 2001-2010 and the Way Forward. New York and Geneva: United Nations

[14] Article 02 of law N° 007/2021 of 5/02/2021 governing companies in Rwanda

Foreign direct investments include long-term physical investments made by a company in a foreign country, such as opening plants or purchasing buildings. Foreign indirect investment involves corporations, financial institutions, and private investors that purchase shares in foreign companies that trade on a foreign stock exchange[15]. Commercial loans are another type of foreign investment and involve bank loans issued by domestic banks to businesses in foreign countries or the governments of those countries[16].

### 2.3. The East African Community (EAC)

The East African Community (EAC) is the regional intergovernmental organization of the Republics of Burundi, Kenya, Rwanda, the United Republic of Tanzania, and the Republic of Uganda, with its headquarters in Arusha, Tanzania. The Treaty for Establishment of the East African Community was signed on 30 November 1999 and entered into force on 7 July 2000 following its ratification by the original three Partner States Kenya, Tanzania and Uganda[17]. The Republic of Rwanda and the Republic of Burundi acceded to the EAC Treaty on 18 June 2007 and became full Members of the Community with effect from 1 July 2007[18].

### 2.4. THE NOTION ON INVESTMENT

On this section I am going to explain the word origin, history, definition and types of investment.

[15] WIR11. World Investment Report 2011: Non-equity Modes of International Production and Development. New York and Geneva: United Nations 103-134 p

[16] Al-Mazrou Y, Al-Shehri S, and Rao M. (1990) Principles and Practice of Primary Health Care. Al-Helal Press: Riyadh, Saudi Arabia 121-125 p

[17] The 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027

[18] NHHLBI. Managing acute complications of sickle cell disease. In: Evidencebased management of sickle cell disease. Bethesda (MD): National Heart, Lung, and Blood Institute (NHLBI); (2014). p. 31-54.

### 2.5. The word origin, history and definition of investment

The concept of an investment is not clearly established. It may involve the use of capital, technical and managerial skills, patents and other intellectual property as well as a variety of other assets[19].

Historically of investment theory shows the merging of finance, statistics, predictability, and economics into the current investment theory. An analysis of the history of a field clarifies its current paradigms and contrasts them with the previous and the competing paradigms. The notion that investment theory is a young science since the 1960s is flawed. Finance as relevant for investment theory has existed since the thirteenth century. The legitimization in the 1860s of investing in stocks, which until the nineteenth century were associated with gambling, results in efficient market theories[20].

Furthermore, the investment is understood as an asset or item that is purchased with the hope that it will generate income or appreciate in the future. In an economic sense, an investment is the purchase of goods that are not consumed today but are used in the future to create wealth. In finance, an investment is a monetary asset purchased with the idea that the asset will provide income in the future or appreciate and be sold at a higher price[21].

#### 2.5.1. Types of investment

There are many different kinds of investment possibilities, including the domestic and foreign stock markets, bonds, precious metals certificates of deposit, savings accounts, foreign currencies and cash[22].

---

[19] For details you can visite the websitehttp://www.eac.int/index.php?option=com_content&view=article&id=1:to-eac&catid=34:body-text-area&Itemid=53.

[20] Mark Rubinstein, "Corporate Financial Policy in Segmented Securities Markets," Journal of Financial and Quantitative Analysis 8, No. 4 (December 1973), pp. 749–761.

[21] abid

[22] http://www.investopedia.com/terms/i/investment.asp.

### 2.5.2. Active pharmaceutical ingredient

Any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when utilized in the production of a drug, becomes an active ingredient in the drug product. All imported active substances must have been manufactured in compliance with standards of good manufacturing practices at least equivalent to the GMP of the EU[23]. The manufacturing standards in the EU for active substances are those of the 'International Conference for Harmonization[24]. This compliance must be confirmed in writing by the competent authority of the exporting country. This document must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of good manufacturing practices at least equivalent to that in the EU[25].

### 2.5.3. Investor

The investor may be individual but are more often, companies. An individual's nationality is determined primarily by the law of the country whose nationality is claimed. The nationality of corporation is typically determined by the place of its incorporation or by the main seat of its business[26].

### 2.5.4. Foreign investor

Foreign investors can be, in order to conduct economic activities in the country different from his or her country of birth or country of domicile, invest in companies and other organizations

[23] National Pharmaceutical Products pricing and Containment Policy of October 2020

[24] Baseline Guide Vol 1: Active Pharmaceutical Ingredients p10-45

[25] abid

[26] WFH.Guidelines for the management of hemophilia.2nded. Montreal (Quebec): World Federation of Hemophilia; (2012). 74p.

conducting economic activities or services establishing/fund companies and conduct other investments, in accordance with the concerned Country's laws[27].

### 2.5.5. Foreign investment

Foreign investment means Flows of capital from one nation to another in exchange for significant ownership stakes in domestic companies or other domestic assets. Typically, foreign investment denotes that foreigners take a somewhat active role in management as a part of their investment[28]. Foreign investment typically works both ways, especially between countries of relatively equal economic stature[29]. Many see foreign investment in a country as a positive sign and as a source for future economic growth[30].

### 2.5.6. Direct investment

A direct investment is one that gives the investor a controlling interest in a foreign company such a direct investment is also a foreign direct investment (FDI) a common term that will be used in this text[31].

### 2.5.7. Portfolio investment

A portfolio investment is a non-controlling interest in a company ownership of a loan to

another party. A portfolio investment usually takes one of two forms stock in a company or loans to a company or a country in the form of the bonds, bills or notes that the investor purchases[32].

[27] Michael C. Jensen, Journal of Financial Economics 6, pp. 95–101, year, 1978.
[28] British Private Equity and Venture Capital Association (2011). Responsible Investment: A Guide for Private Equity & Venture Capital Firms. London.
[29] No. 41, August 1991 Manuel R. AGOSIN Trade policy reform and economic performance: A review of the issues and some preliminary evidence
[30] who (2008) integrated health systems what and why who service delivery series, technical brief no.1.23-67p
[31] abid
[32] (Daniel p Sullivan 2007; 45).

### 2.5.8. Definition of foreign direct investment

Foreign direct investment (FDI) is defined as an investment involving a long-term relationship and reflecting a lasting interest and control by a resident entity in one economy (foreign direct investor or parent enterprise) in an enterprise resident in an economy other than that of the foreign direct investor. Therefore, foreign direct investment is recognized as an important factor in this context, since it brings to host countries capital, technology, innovation and management know-how, as well as Daniel p Sullivan said, it imply the access to supply chains and new markets[33]. Under the right policy conditions and institutional frameworks, it can thus contribute to economic development and growth[34].

### 2.5.9. Incentives

The only major international instrument that contains a partial definition is the agreement that Governments use to attract investors and to benefit more from it, the incentives may focused on financial incentives, such as outright grants and loans at concessionary rates; · fiscal incentives such as tax holidays and reduced tax rates and other incentives, including subsidized infrastructure or services, market preferences and regulatory concessions, including exemptions from labor or environmental standards. Incentives can be used for attracting new FDI to a particular host country (locational incentives) or for making foreign affiliates in a country undertake functions regarded as desirable such as training, local sourcing, research and development or exporting (behavioral incentives)[35]. Most incentives do not discriminate between domestic and foreign investors, but they sometimes target one of the two. In some countries, such as Ireland, the entire incentive scheme was geared to FDI for a long period.

[33] UNCTAD (2011a). "Global investment trends monitor. No. 5, 202-206 p.
[34] World Economic Outlook, April 2007, 57-81p
[35] Transnational Corporations in the 1990s. 224 p. Published by International Thomson Business Press on behalf of UNCTAD.

Incentives may also favor small firms over large, or vice versa. They are offered by national, regional and local governments[36].

### 2.5.10. THE GENEARAL NOTION ON THE INTERNATIONAL INVESTMENT LAW.

This section deals with the sources of international investment law and historical background of international investment agreement[37].

### 2.5.11. INTERNATIONAL INVESTMENT LAW

On this section, the international investment law comprises of bilateral investment Treaties, multilateral investment agreement, international customary law, international investment principle[38].

### 2.5.12. Bilateral Investment Treaties

The most important source in contemporary investment law is bilateral investment treaties. The first country to start entering into Bilateral Investment Treaties was Germany in 1959, closely followed by Switzerland in 1961. Other country has followed suit. It is estimated that by 2008 there were about 2600 Bilateral Investment Treaties (BITs) Worldwide, Bilateral Investment Treaties are designed to provide guarantees for foreign investors from the respective countries. They do not normally address obligations of investors, although some Bilateral Investment[39]. Treaties provide those investments; in order to be protected must be in accordance with the host states law[40].

---

[36] ibid

[37] Vo D, Cherian MN, Bianchi S, et. Al. Anesthesia capacity in 22 low- and middle-income countries. (2012). J AnesthClin Res. 3:4. http://dx.doi.org/10.4172/2155- 6148.1000207.

[38] foreign investment law, rm official gazette, no. 52/00

[39] Rwanda MoH. (2012). Pediatric Clinical Treatment Guidelines. Ministry of Health: Kigali, Rwanda

[40] Unated nations, An investment guide to the East African Community: Opportunities and conditions, New Yorkand Geneva.

The first efforts to create a multilateral treaty protecting foreign investments dates back to the 1950s and 1960s. Between 1995 and 1998 the Organization for Economic Co-operation and development (OECD) launched a new initiative to establish a Multirateral Agreement on Investment (MAI). The breakdown of this effort was caused by a number of factors, including widespread opposition by nongovernmental organizations and the desire of France to protect French culture. An effort in the framework of the World Trade Organization (WTO) started in 1996 but came to a halt in 2004[41]. The main reason was the fear of developing countries that a multilateral treaty might narrow their regulatory space[42].

### 2.5.13. Customary International Law as tool used in pharmaceutical industries

A widespread custom is a source of international law, as it expresses opinion juris within the international community that the principle involved is obligatory. There are few customs in this sense in the field of foreign investment. There is, however, a custom that, when property is taken over by a state, otherwise than in the exercise of its regulatory powers, there must be payment of compensation, though there is still no agreement on the manner in which this compensation is to be calculated[43]. Developing states have used their numerical strength in the General Assembly to adopter solutions in the area of foreign investment[44].

The extent to which such resolutions can create international law has been a matter of intense debate. The view has been expressed that the principles contained in General Assembly resolutions constitute „instant customary international law" in that they are evidence of an opinion juris of the international community formed at a solemnly constituted assembly[45].

[41] Thomas Bayes (circa 1701–April 7, 1761)
[42] http://unctad.org/e n/ docs, pdf
[43] World Economic Situation and Prospects 2002. 51 p. publication with the United Nations Department of Economic and Social Affairs.
[44] Bhagwati, J. and R.A. Brecher. "National Welfare in an Open Economy in the Presence of Foreign Owned Factors of Production." Journal of International Economics 19 (1980): 103–115.
[45] Supranote34

However, the proposition was initially formulated in the context of, and was confined to, areas that were not governed by existing legal norms. There is also the view that frequently asserted resolutions of the General Assembly have a law-creating effect[46]

Customary International Law also plays an important role in investment law. The international minimum standards for the treatment of aliens are still relevant in a number of contexts including denial of justice. State responsibility is another area of international law that is frequently applied in cases involving the protection of investments. International rules on the nationality of individuals and corporations are sometimes important in determining the applicability of treaties[47].

### 2.5.14. International investment principle

The main principles on this section are the fair and equitable treatment standard, Most-favored-nation treatment, Nationalization and fair compensation.

### 2.5.15. National standard of treatment for pharmaceutical industries from East Africa

The notion of nation treatment could be understandable as the important right, as it entitles the foreign investor to a right of entry and establishment in the host state. Treaties which aim at liberalization contain such pre-entry rights of establishment and granting of national treatment after entry may confer advantages on aliens, as it will grant them the same privileges enjoyed by nationals[48]

[46] *European Journal of International Law*, Volume 16, Issue 5, November 2005, Pages 879–906
[47] Abid
[48] International Investment Arrangements: Trends and Emerging Issues. 110 p

### 2.5.16. Fair and equitable treatment standard of pharmaceutical industries

In general, there is no common definition of this principle some others like sufficiently noted that the fair and equitable treatment standard has been expanded to include notions of transparency and legitimate expectations of the foreign investor. But, as has been pointed out, if notions of fairness are to be taken into account, they would make the context in which the fairness is to be assessed relevant so that the standard would require taking into account whether or not the state interference was in response to the malpractices of the multinational corporation[49].

### 2.5.17. Brand/innovator drug

A pharmaceutical product that has a trade name and is protected by a patent (it can be produced and sold only by the company holding the patent). Manufacturers seeking approval to market a generic drug product must submit data demonstrating that the generic formulation provides the same rate and extent of absorption as the innovator drug product. Most bioequivalence studies are conducted on the high strength of a drug product line, unless it is necessary to use a lower strength for safety reasons[50]. Use of the highest strength is particularly critical for drugs that display nonlinear kinetics because of nonlinear (usually capacity-limited) elimination or presystolic metabolism, for which the extent of absorption increases more than proportionally with an increase in dose. pharmaceutically equivalent to an approved safe and effective reference product in that it contains identical amounts of the same active drug ingredient in the same dosage form and route of administration and meets compendia or other applicable standards of strength, quality, purity, and identity; bioequivalent to the reference product in

[49] Biggs, Tyler. Conversation. Washington, DC: World Bank, May 22, 1997 B. Cheng, „United Nations Resolutions on Outer Space: Instant International Customary Law' (1965)5IJIL23

that it does not present a known or potential bioequivalence problem and it meets an acceptable in vitro standard(usually dissolution testing) or if it does present such a known or potential problem, it is shown to meet an appropriate bioequivalence standard; adequately labelled; and manufactured in compliance with current Good Manufacturing Practice regulations[51]. The regulatory oversight of generic drug chemistry, manufacturing, and controls is identical to that imposed upon innovator drug products[52].

### 2.5.18 Counterfeit drugs

These are forged or altered pharmaceutical products. They may be contaminated, contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose. These illegal drugs are a health risk to patients. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals medicines manufactured below established standards of safety, quality and efficacy. They are deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients. Until recently, the most frequently counterfeited medicines in wealthy countries were new, expensive lifestyle medicines, such as hormones, steroids and antihistamines[53]. In developing countries, the most counterfeited medicines have been those used to treat life threatening conditions such as malaria, tuberculosis and HIV/AIDS. As the phenomenon spreads, more and more medicines are counterfeited, including expensive ones, such as anticancer drugs, and those highly in demand, such as antivirals. Measures for combating counterfeit medicines so far have included actions taken by drug regulatory

[51] Buckley, Peter J., and Mark Casson. The Future of the Multinational Enterprise. London: Macmillan, 1976 and 1978.
[52] Binnendijk, H. National Negotiating Styles. Washington, DC: Foreign Service Institute, US Department of State, 1987.
[53] International Investment Agreements in Services. 119 p

authorities and cooperation initiatives between different law enforcement agencies; providing simple, easily interpretable and cheap markers of authenticity; coordinating international surveillance for fake and substandard drugs; and educating patients and healthcare workers[54]. Legislation forms the basis for drug regulation. Medicines need to be safe, effective and of good quality in order to produce the expected therapeutic effect. Ensuring these properties requires the creation of competent national drug regulatory authorities with the necessary human and other resources to control the manufacture, importation, distribution and sale of medicines. Legislation must be complemented with effective law enforcement. Governments need to develop strategies to reduce corruption and criminal activity and promote interpectoral cooperation between regulatory authorities, police, customs services and the judiciary to effectively control the drug market and enforce drug regulation. When that regulation is infringed, sanctions against the manufacture and distribution networks must be commensurate to the crime[55].

### 2.5.19. Finished pharmaceutical product

A pharmaceutical product that has been subjected to all the stages of production and testing, including packaging in its final container and labelling.

Quality characteristics cover the following area, general characteristics of the pharmaceutical form, particularly pharmaceutical that is to say those characteristics, determined in general by physical tests with limits of acceptance, relating to the product performance or handling (e.g. hardness, friability of a conventional tablet); identification of the active substance(s), if necessary, identification and assay of the excipients such as identification of colorants used, identification and assay of antimicrobial agents or antioxidant preservatives (with acceptance

[54] Incentives. 108 p.
[55] James A. Ohlson, "Earnings, Book Values, and Dividends in Equity Valuation," Contemporary Accounting Research 11, No. 2 (Spring 1995), pp. 661–687.

limits); purity tests (if necessary, the investigation of breakdown products, residual solvents or other process related impurities, microbial contamination);pharmaceutical tests (e.g. dissolution) safety tests including abnormal or specific toxicity tests, where applicable, in particular for biological products. In order to determine the specifications of the finished product, the quality characteristics related to the manufacturing process should be taken into account. An appropriate specification for each aspect of quality studied during the phase of development and during the validation of the manufacturing process should be determined. At least those aspects considered to be critical should be the object of specifications routinely verified[56].

In certain cases, for characteristics of the medicinal product which may change during storage under the approved conditions, the quality required at the end of shelf life should be taken into account in determining appropriate specifications at the time of manufacture, for example in the case of overages for reasons of stability. It is desirable that all specifications (characteristics and acceptance limits) of the medicinal product and the finished product at the time of release be presented in the form of a summary table. In this table, the limits of any likely breakdown products which may form under the approved conditions of storage should be stated[57].

**2.5.20. Free trade area**

A region encompassing a trade bloc whose member countries have signed a free trade agreement. Such arrangements involve cooperation between at least two countries to reduce trade barriers import quotas and tariffs – and to increase trade of goods and services with each other. Article 3 agreement establishing the African Continental free trade area stipulate the general objectives that are the following:

[56] Last revised 1991 Previous titles/other references Control of the Finished Product/ III/3324/89
[57] abid

(a) Create a single market for goods, services, facilitated by movement of persons in order to deepen the economic integration of the African continent and in accordance with the Pan African Vision of "An integrated, prosperous and peaceful Africa" enshrined in Agenda 2063;

(b) Create a liberalized market for goods and services through successive rounds of negotiations;

(c) Contribute to the movement of capital and natural persons and facilitate investments building on the initiatives and developments in the State Parties and RECs;

(d) Lay the foundation for the establishment of a Continental Customs Union at a later stage;

(e) Promote and attain sustainable and inclusive socio-economic development, gender equality and structural transformation of the State Parties;

(f) Enhance the competitiveness of the economies of State Parties within the continent and the global market;

(g) Promote industrial development through diversification and regional value chain development, agricultural development and food security; and

(h) Resolve the challenges of multiple and overlapping memberships and expedite the regional and continental integration processes[58].

### 2.5.21. Generic drug

A generic drug is a pharmaceutical drug that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance and intended use. In most cases, generic products become available after the patent protections afforded to a drug's original developer expire. In medicines regulation and in WHO prequalification, the efficacy of generics is demonstrated by bioequivalence studies[59]. WHO medicines prequalification has facilitated

[58] Article 3 establishing the African Continental free trade area

[59] China, National Bureau of Statistics (2012). China Statistical Yearbook 2011. Beijing: China Statistical Press

academic research, and has itself been a subject of academic research[60]. Adjusted indirect comparisons were conducted, using the results of separate bioequivalence studies for WHO-prequalified generics against the same comparator product. The comparisons found that the generics can be considered as clinically equivalent among each other[61]. Recommendations are provided for regulatory assessment of generics in WHO Member States and for possible approaches to harmonization of bioequivalence requirements to facilitate access to needed products[62].

### 2.5.22. Good practices

The agreed description of the pharmaceutical organization, procedures and standards that enable the required quality of service to be delivered, including criteria for organizational structures, personnel, facilities, equipment, materials, all kind of operations, quality control, Generic medicines can enable huge cost-savings as they create competition, driving down prices. A "Best Practice" is commonly defined as "a technique or methodology that, through experience and research, has proven reliably to lead to a desired result[63].

The term is used frequently in areas such as health, government administration, the education system, project management, and others. In the context of health programmers and services, a practical definition of a Best Practice is knowledge about what works in specific situations and contexts, without using inordinate resources to achieve the desired results, and which can be used to develop and implement solutions adapted to similar health problems in other situations and contexts[64]. The use of the word best should not be considered in the superlative sense. In other words, the term Best Practice is not about perfection, the gold standard or only elements

[60] Winham, Gilbert R. "Multilateral Economic Negotiation." Negotiation Journal (April 1987): 175–189.
[61] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm under International Conference on Harmonization Quality
[62] The World Health Organization's Prequalification of Medicines Programmed. J Public Health Policy. 2014: 35(2): 137–61.
[63] WHO Technical Report Series No. 992, Geneva: World Health Organization; 2015.
[64] WHO Technical Report Series No. 992, Geneva: World Health Organization; 2015.

that have been shown to contribute towards making interventions work or successful. Results can be partial and may be related to only one or more components of the practice being considered[65]. Indeed, documenting and applying lessons learned on what does not work and why it does not work is an integral part of Best Practice so that the same types of mistakes can be avoided by other programmers and projects[66].

There are several creative and constructive actions by people and organizations in the health sector to improve health outcomes of people. Making knowledge of such actions widely available may prevent the repetition of mistakes and loss of valuable time. Thus, the main rationale for documenting and sharing "Best Practices is to enable persons and organizations working in the health sector to avoid re-inventing the wheel to learn in order to improve performance and to avoid the mistakes of others. Documenting and sharing Best Practices affords one the opportunity to acquire knowledge about lessons learned and to continue learning about how to improve and adapt strategies and activities through feedback, reflection and analysis in order to implement larger-scale, sustained, and more effective interventions[67]. A commitment to using a Best Practice is a commitment to using the body of knowledge and technology at one's disposal to ensure success[68].

### 2.5.23. Harmonization

The name given to the effort by member States to replace the variety of national pharmaceutical policies, practices and standards currently adopted in favour of uniform regional policies, "good practices" and standards, which are at an internationally acceptable level[69].

---

[65] Developments in Investor–State Dispute Settlement. http://www.unctad.org/en/docs/.pdf
[66] WHO Drug Information Vol. 30, No. 3, 2016
[67] World Bank. The East Asian Miracle: Economic Growth and Public Policy. New York: Oxford University Press, February 1994 (First printing 1993).
[68] Understahl, B., 2006. Authorized Generics: Careful Balance Undone. 16 Fordham Intell. Prop. Media & Ent. L.J., pp. 355-393.
[69] http://dspace.onua.edu.ua/handle/11300/12616.

### 2.6. Health products

Health products include other pharmaceutical and health-related products (such as bed nets, laboratory and radiology equipment, and supportive products), as well as single-use health products (such as condoms, rapid and non-rapid diagnostic tests, insecticides and injection syringes[70].

#### 2.6.1. Intellectual property rights

Exclusive rights of a person or company to use their plans, ideas or other intangible assets without the worry of competition, at least for a given period. These rights can include copyrights, patents, trademarks and trade secrets. A court may enforce these rights via a lawsuit[71]. The reasoning for intellectual property is to encourage innovation without the fear that a competitor will steal the idea and take the credit for it[72].

#### 2.6.2. Pharmaceutical industry

A manufacturing industry that is engaged in the research, development, manufacture and marketing of drugs and biologicals for human and veterinary use. These companies may be involved in the production of brand or generic medicines as well as medical devices[73]. They are governed by a variety of laws relating to the patenting, testing, safety, efficacy and marketing of pharmaceutical products[74].

---

[70] Ahmed, A.K. (2011). *An Analysis of Regional Integration in Southern Africa: A South African Perspectiv*e. Tralac Paper. Western Cape. South Africa.

[71] Paris Convention for the Protection of Industrial Property adopted 1883

[72] abid

[73] National Pharmacy Policy of April 2016

[74] Chibisov, D. M. (2017). Protection of intellectual property rights within the World Trade Organization. Odesa: Phoenix. In http://hdl.handle.net/11300/7382.

### 2.6.3. Pharmaceutical market

An actual or theoretical place where forces of demand and supply operate, and where buyers and sellers interact (directly or through intermediaries) to trade pharmaceutical products, medical devices, services and contracts for money or barter[75].

### 2.6.4. Pharmaceutical procurement and supply management system

This system is composed of all steps in the procurement and supply system: selection, quantification, shopping, tendering, negotiation, ordering, storing, selling, distributing and dispensing of essential medicines and medical supplies[76].

## 2.7 Pharmaceutical products

These include an active pharmaceutical ingredient in their finished dosage form that is intended for human use[77].

### 2.7.1. Protectionist policies

Policies that seek to shield a country's domestic industries from foreign competition by taxing imports[78]

### 2.7.2. Quality assurance

The quality assurance of pharmaceutical products is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of

[75] Raisch DW. A model of methods for influencing prescribing: part ii. a review of educational methods, theories of human inference and delineation of a model. DICP. 1990;24(5):537-542
[76] Manchanda P, Honka E. The effects and role of direct-to-physician marketing in the pharmaceutical industry: an integrative review. Yale J Health Policy Law Ethics. 2005; 5(2):785-822
[77] abid
[78] abid

the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use[79].

### 2.7.3. Quality control

The quality control of pharmaceutical products is a concept that covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that the raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics[80].

### 2.7.4. Research and development

Investigative activities a business conducts to improve existing products and lead to the development of new products and procedures.

### 2.7.5. Standardization

The process of establishing a technical standard, which could be a standard specification, standard test method, standard definition, or standard procedure. Standardization means that there is a standard specification, unit, instruction or something that is understood globally[81].

### 2.7.6. Technology transfer

The transfer of new technology from the originator to a secondary user, especially from developed to developing countries, in an attempt to boost their economies[82].

[79] https://www.hsa.org.ua/blog/obrobka-personalnyh-danyh-v-umovah-covid-19- zahyst-chy-porushennya-prav-lyudyny/.
[80] Buletsa, S. B. (2020). Features of the contract of controlled access in the conditions of Covid-19. In http://dspace.onua.edu.ua/handle/11300/12616.
[81] Service, R. F. (2020). Would-be coronavirus drugs are cheap to make. Science. Inhttps://www.sciencemag.org/news/2020/04/would-be-coronavirus-drugs-arecheap-make.
[82] ia Opara & Oleg Tsybokhin | v. 9 (II) (2019), p. 288 https://www.researchgate.net/publication/313860747

### 2.7.7. Tracer medicines

Medicines selected by the surveyors in the 2010 Pharmaceutical Marketing Analysis study, of which the assembled data form the baseline for measuring implementation of the strategy[83].

## 2.8. Health Security and Pharmaceutical Production in East Africa

Local production is essential for improved access to affordable medical products, and therefore to ensure a strong linkage between local production and improved access, there is need to bring coherence between health, industrial development and trade policies in the pharmaceutical sector[84].

Development of the pharmaceutical industry in East Africa contributes to building more robust and sustainable national health systems. Local production broadens supplier base, reduces foreign currency expenditure and helps local producers to improve their response to local needs. A stronger local pharmaceutical industry improves a country's capacity to respond to local health priorities and creates synergies and linkages between industrial and health system investments[85]. By developing the local pharmaceutical industry, throughout EAC-RPMPOA by 2012–2016, East African governments increase local value addition through better backward and forward linkages for example the packaging, excipients and distribution services [86].

The issues surrounding public health provide an important perspective on the local production of medicines in East Africa. This requires the alignment of industrial development and public

[83] Shirsat, M.K. (2011). Drug Patent System in India and its Application. Asian Journal of Pharmaceutical and Clinical Research, 1(1), 13-24.

[84] Cleopa Mailu, Cabinet Secretary Ministry of Health Kenya (UNAIDS 2016)

[85] Division on Investment, Technology and Enterprise Development United Nations Office in Geneva Palais des Nations Room E-9123 CH-1211 Geneva 10 Switzerland Fax: 41-22-907-0194

[86] *Competition Policy International, Antitrust Chronicle Competition Policy*, Spring 2014, Vol. 3, No. 2.

health objectives. The development of local medicine production is a priority for local consumers[87].

African leaders have laid down the importance of the promotion of the pharmaceutical sector in the AU Pharmaceutical Manufacturing Plan for Africa (PMPA) and the Business Plan for the accelerated implementation (AU 2012). The pharmaceutical sector has been identified as a priority sector in industrial development initiatives such as the Third Industrial Development Decade for Africa (IDDA III) and the Accelerated Industrial Development of Africa (AIDA)[88]. At the regional level development plans for the sector have been formulated like the 2nd East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) 2017-2027 and the ECOWAS Regional Pharmaceutical Plan (ERPP) 2014-2020. At the national level many governments are considering to prioritize the sector which can bring potential benefits in the health and industrial development spheres[89].

### 2.8.1. Cost of Production

East African manufacturers suffer from several cost disadvantages including: higher unit costs associated with manufacturing, materials and machinery, finance and utility services. The small scale of most SSA producers also tends to increase the unit costs of production. Foreign firms with large manufacturing plants serving bigger markets can economise on costs with larger production batch sizes and can 'afford' dedicated facilities for particular formulations, which saves costs of change over between products. A firm with a larger plant producing larger volumes can also buy materials at lower prices[90]. Unit labour costs in East Africa are generally higher due to lower productivity and higher cost for hiring technically qualified people and

[87] Monitor No. 2 (2007): Development implications of international investment agreements.
[88] Wang, B., Liu, J. & Kesselheim, A., 2015. Variations in Time of Market Exclusivity Among Top-selling Prescription Drugs in the United States. JAMA Internal Medicine, 175(4), pp. 635-637. doi:10.1001/jamainternmed.2014.7968.
[89] abid
[90] Dolzer, R. and Schreuer, C. (2008). Principles of International Investment Law (Oxford: University Press).

experts from abroad[91]. East African manufacturers rely on imported sources for most of their requirements of APIs, excipients, primary packaging materials, machinery and equipment. Import duties and value added tax (VAT) on these materials and equipment increase the cost in many countries while imported medicines are often exempt from duties and taxes[92].

### 2.8.2. Economics of Intellectual Property

In countries where there is strong generic competition, processes for challenging/enforcing patents are critically important. From the perspective of patent holders, the ability to recover lost profits from infringers or to obtain preliminary injunctions against alleged infringers while litigation proceeds are very important factors affecting the return on R&D. From the perspective of would-be entrants (and payers) the ability to have patents declared unenforceable or invalid, or to oppose applications for patents, or to counter-sue patent holders on the basis of violation of competition law or unfair trading practices are equally important. For both sides, the availability of timely, non-discriminatory, transparent and predictable processes for resolving patent disputes is also a material issue, as is "patent quality" inconsistently or poorly applied standards for patentability are likely to raise the costs and uncertainty faced by all parties affected by patents[93]. For any product, the strength of patent protection in a country is also affected by the interaction between domestic IPRs and trade law. This is particularly important in pharmaceuticals, where transportation costs are very low relative to the value of the product, and high-quality manufacturing capacity is geographically concentrated. Provisions governing national exhaustion of IPRs, "reimportation" and parallel

[91] World Bank. Private Capital Flows to Developing Countries: The Road to Financial Integration. New York: Oxford University Press, April 1997.
[92] http://www.cuts-international.org/pdf/CCIER-3-2008.pdf, accessed 17 August 2023.
[93] Baker, B.K., 'A Critical Analysis of India's Probable Data Exclusivity/ Data Compensation Provisions', Health Gap, available at www.healthgap.org, 2004.

trade are one important area, as is the ability of patent holders to use customs procedures and trade dispute mechanisms to exclude competitors[94].

A subsidiary trade-related issue is the extent to which a country allows "product by process" protection, namely the right to exclude imports of an unpatented or unpatentable drug product (for example, a naturally occurring protein) if it has been produced abroad using a process that is patented in the domestic market. Finally, patent protection for pharmaceuticals is affected in some countries, at least in principle, by provisions to issue compulsory licenses in public health emergencies, or in furtherance of other national priorities[95].

### 2.8.3. Term of market exclusivity

Patent term Market exclusivity provided by regulatory approval Patent/exclusivity extensions to compensate for regulatory review delays Extensions for pediatric investigation Extensions for orphan drugs Extensions for drugs targeting specific diseases[96].

### 2.8.4. Patentability standards

Patent document (ref. Certificate of registration), describes an invention and creates a legal situation for exploitation of the invention, industrial applicability, Intellectual Property, as Rights over a scientific or technological invention, where Patentable Subject Matter is any inventions, in all fields of science and technology[97].

[94] Graboswski, H., 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries', Duke University, July 2002.
[95] Biesebroeck, V. &Broocks, A. (2017).The impact of export promotion on export market entry. *Journal of International Economics*, Elsevier, vol. 107(C), pages 19-33.
[96] Busch P, Wilson D. An experimental analysis of a salesman's expert and referent bases of social power in the buyerseller dyad. J Mark Res. 1976;13(1): 3-11.
[97] Berne Convention

### 2.8.5. Restrictions on imitators

There is some evidence that intellectual property rights, in the form of patents and trademarks, are relatively more important in the pharmaceutical industry than in other sectors. One survey of several industries ranked the pharmaceutical industry the highest in its reliance on patent protection. This may be affected due to the fact that patents on prescription drugs are a more effective means of raising imitation costs than patents on other products[98]. That why there must be an institution in charge of having skills to block product by process imports, having ability to block testing of production processes, having ability to block stockpiling of patented products by generics in advance of patent expiration and ability to block reimportation or parallel trade[99].

Patents play a critical role in stimulating and rewarding research and innovation in the pharmaceutical industry. The role of intellectual property rights in modern industrial society is so fundamental as to be largely taken for granted. However, it is useful to recall that patent protection of pharmaceuticals (like patent protection of other products) has both advantages and disadvantages. The primary disadvantages of patent protection are its bluntness as a policy instrument and the resulting market power which it generates. The primary advantages are its efficient use of information and the fact that the patent process makes new innovations public information[100].

### 2.8.6. Obligations of patentees

A patent is a statutory grant giving certain syndication rights on the grantee for a characterized period, subject to specific conditions. In some regard it might be considered as a type of

[98] Gwaza L, Gordon J, Potthast H, et al (2015)
[99] Understahl, B., 2006. Authorized Generics: Careful Balance Undone. 16 Fordham Intell. Prop. Media & Ent. L.J., pp. 355-393.
[100] U.S. Food and Drug Administration, 2020d. Product-Specific Guidances for Generic Drug Development. [Online] Available at: https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm.

property. A patent grant gives the patentee the exclusive ideal to make or utilize the patented article or utilize the patented procedure. As an outcome spilling out of this, he can keep all others from making or utilizing the patented article or utilizing the patented procedure. A patent imposing business model not just qualifies the holder for endeavor the innovation without rivalry amid the time of patent insurance; it additionally empowers him to enter the market, on the expiry of the restraining infrastructure in a solid position. A patentee has likewise the ability to appoint the patent, grant licenses under, or generally manage it for any thought[101]. These rights made by the rule are encompassed by different conditions and constraints[102].

Patent document (ref. Certificate of registration) describes an invention and creates a legal situation for exploitation of the invention. Patent rights: IP Rights over a scientific or technological invention, Patentable Subject Matter: any inventions, in all fields of science and technology, Some exceptions[103].

### 2.8.7. Enforcement/challenge mechanisms for all IPRs

Challenges in IPR Enforcement in Worldwide[104], in Africa and in Rwanda are, limitation of enforcement mechanisms- anti piracy policy squad inadequate coordination between enforcement agencies[105]. Lack of linkage and information exchange between IP office & enforcement agencies and inadequate awareness of the adverse impact of counterfeits and piracy, online piracy advancement of technology etc.[106].

[101] sprequalified by WHO. Eur J Clin Pharmacol. 2012, 412 p.
[102] Section 48 of the Patent Act, 1970, article 28
[103] Article 14, of the law n° 31/2009 of 26/10/2009 on the protection of intellectual property
[104]Uganda National Pharmaceutical Sector Strategic Plan II 2015–2020.
[105] Amin, A.A. (2013). African Development: Institutions, Economic Reforms and Growth. International Journal of Economics and Financial Issues 3(2), 324-336.
[106] Socal, M., Bai, G. & Anderson, G., 2019. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics are Available. JAMA Internal Medicine, 179(6), pp. 832-833

## 2.9. Trademarks

A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks are protected by intellectual property rights. The main function of a trademark is to enable consumers to identify a product (whether a good or a service) of a particular company so as to distinguish it from other identical or similar products provided by competitors[107].

Consumers who are satisfied with a given product are likely to buy or use the product again in the future. For this, they need to be able to distinguish easily between identical or similar products. By enabling companies to differentiate themselves and their products from those of the competition, trademarks play a pivotal role in the branding and marketing strategies of companies, contributing to the definition of the image, and reputation of the company's products in the eyes of consumers. The image and reputation of a company create trust which is the basis for establishing a loyal clientele and enhancing a company's goodwill[108]. Consumers often develop an emotional attachment to certain trademarks, based on a set of desired qualities or features embodied in the products bearing such trademarks[109]. Trademarks also provide an incentive for companies to invest in maintaining or improving the quality of their products in order to ensure that products bearing their trademark have a positive reputation[110].

### 2.9.1. Special provisions

Samples of new or existing pharmaceutical substances or articles may be transported as directed by the competent authorities for purposes including: testing, classification, research

[107] *Qualitex Co. v. Jacobson Products Co., Inc.*, 514 U.S. 159 (1995); *In Re Owens-Corning Fiberglass Corp.,* 774 F.2d 1116 (Fed. Cir. 1985); *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992).
[108] Busse, M.&Jens, K. (2012). Trade and Economic Growth: A Re-examination of the Empirical Evidence. HWWI Research Paper no. 123.
[109] *reyhound Corp. v. Both Worlds, Inc. d.b.a. The Wild Berry,* 6 U.S.P.Q.2d (BNA) 1635 (TTAB 1988)
[110] abid

and development, quality control, or as a commercial sample[111]. Explosive samples which are not wetted or desensitized shall be limited Even though this substance has a flammability hazard, it only exhibits such hazard under extreme fire conditions in confined areas[112].

### 2.9.2. Corruption in prescribing medicines

It has already become a common practice for officials and company representatives to systematically provide doctors of healthcare institutions with unlawful benefits, for which doctors, using their powers, when prescribing drugs to patients, preferred the drugs of this particular group of companies. This practice of prescribing expensive drugs from specific manufacturers and a heap of unnecessary/overlapping drugs to their patients "on the load" in prescriptions by doctors is especially aggravated during economic crises. The purchasing power of Ukrainians is falling sharply, but at the same time, the profits of pharmaceutical companies are paradoxically growing steadily[113]. For example, this was the case during the crisis of 2008- 2009, when, according to experts, Ukrainians overpaid for medicines up to one billion dollars, purchasing expensive medicines on the advice of doctors instead of analogs that are in no way inferior in their properties[114].

In the same way, the Ministry of Healthcare has been taking various measures from time to time for more than a dozen years, "demonstrating" its readiness to fight these corruption schemes. Precisely by demonstrating since corruption schemes involving pharmaceutical companies have successfully survived more than one minister of health and more than one government. In particular, the Ministry of Health has repeatedly tried to prohibit doctors from

---

[111] Sphere Project. Minimum Standards in Water Supply, Sanitation and Hygiene Promotion. (2010). Available at: http://www.spherehandbook.org/content/pages/ en/6.minimum-standards-in-water-supply-sanitation-and-hygiene-promotion.pdf

[112] J Public Health Policy. 2014: 35(2): 137–61.

[113] Chidede, T. (2018).World Trade Organization Trade Facilitation Agreement: An African Perspective. Accessed from: https://www.tralac.org/blog/article/13680-wto-tradefacilitation-agreement-an-african-perspective.html.

[114] UNCTAD (2011) Local Production of Pharmaceuticalsand Related Technology Transfer in DevelopingCountries - A series ofcase studies by the UNCTADsecretariat, UNCTAD Geneva

indicating the trade name of a medicine in prescription doctors were allowed to indicate only the active ingredient in the prescription so that the patient could already be in the pharmacy decide for himself what kind of drug with such a substance he will choose and buy[115]. The success of this company is very moderate, given the latest high-profile cases with "promotions" exposure of the national police to a scheme of bribery of doctors[116].

### 2.9.3. Trade imbalance

Another unpleasant feature of the domestic pharma market is a significant imbalance between products manufactured by national companies and foreign ones. Looking at Figure 1, we can observe the situation, when national companies dominate in all quantitative indicators, but foreign drugs account for the bulk of the money turnover. There are two opposing opinions to explain this situation[117]. Representatives of foreign companies refer to the fact that Ukraine imports more complex and expensive drugs by default, plus logistics, licensing, and customs fees are imposed on this issue[118]. Domestic companies, however, are called the main reason the existence of exclusive patent rights to many formulas, modifications, and production methods of drugs that foreign companies use to get high income and prevent them from joining the game and producing cheap similar drugs[119].

### 2.9.4. Pharmaceutical development

The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product[120]. The information and

[115] Ministry of Trade and Industry (2017). Made in Rwanda Policy. Kigali-Rwanda
[116] SM Flynn, 2014, Using Competition Law to Promote Access to Medicines, https://www.wcl.american.edu/pijip/download.cfm?downloadfile=34080B0A-C32A-6A22-22ED8491FC3EB62B.
[117] Glossary of foreign direct investment terms and definitions. (n.d.). Retrieved October 3, 2019, from OECD website: https://www.oecd.org/daf/inv/investmentpolicy/2487495.pd
[118] Saha, A. et al., 2006. Generic Competition in the US Pharmaceutical Industry. International Journal of the Economics of Business, 13(1), pp. 15-38.
[119] ICH guideline Q8 (R2) on pharmaceutical development EMA/CHMP/ICH/167068/2004
[120] ibid

knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the design space*****, specifications, and manufacturing controls[121]. Information from pharmaceutical development studies can be a basis for quality risk management. It is important to recognize that quality cannot be tested into products; i.e., quality should be built in by design. Changes in formulation and manufacturing processes during development and lifecycle management should be looked upon as opportunities to gain additional knowledge and further support establishment of the design space. Similarly, inclusion of relevant knowledge gained from experiments giving unexpected results can also be useful. Design space is proposed by the applicant and is subject to regulatory assessment and approval[122]. Working within the design space is not considered as a change[123]. Movement out of the design space is considered to be a change and would normally initiate a regulatory post approval change process[124].

### 2.9.5. Drug substance

The physicochemical and biological properties of the drug substance that can influence the performance of the drug product and its manufacturability, or were specifically designed into the drug substance solid state properties, should be identified and discussed.

Examples of physicochemical and biological properties that might need to be examined include solubility, water content, particle size, crystal properties, biological activity, and

[121] Baker, B.K., 'A Critical Analysis of India's Probable Data Exclusivity/ Data Compensation Provisions', Health Gap, available at www.healthgap.org, 2004.
[122] Vijayasri, G.V. (2013). Trade Liberalization and the Theory of Endogenous Protection: An Econometric study of United States Import Policy. International Journal of Marketing, Financial Services and Management Research. Vol2. No. 9 (pp111-115)
[123] Warman 2020, published in 119(8), pp. 769-833
[124] Graboswski, H., 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries', Duke University, July 2002.

permeability[125]. These properties could be inter-related and might need to be considered in combination[126.]

## 2.10. Drug product

### 2.10.1. Formulation development

A summary should be provided describing the development of the formulation, including identification of those attributes that are critical to the quality of the drug product, taking into consideration intended usage and route of administration. Information from formal experimental designs can be useful in identifying critical or interacting variables that might be important to ensure the quality of the drug product[127]. The summary should highlight the evolution of the formulation design from initial concept up to the final design. This summary should also take into consideration the choice of drug product components (e.g., the properties of the drug substance, excipients, container closure system, any relevant dosing device), the manufacturing process, and, if appropriate, knowledge gained from the development of similar drug product(s)[128].

### 2.10.2. Excipients

This should include all substances used in the manufacture of the drug product, whether they appear in the finished product or not. Compatibility of excipients with other excipients, where relevant (for example, combination of preservatives in a dual preservative system), should be established. The ability of excipients (e.g., antioxidants, penetration enhancers, disintegrants, release controlling agents) to provide their intended functionality, and to perform throughout

[125] Technical Report Series No. 992, Geneva: World Health Organization; 2015.
[126] UNGA, 'International Covenant on Economic, Social and Cultural Rights' (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 12
[127] World Trade Organization (1994). Trade-Related Aspects of Intellectual Property Rights. In https://www.wto.org/english/tratop_e/trips_e/trips_e.htm.
[128] Pugatch, M.P., 'Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access', ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, Italy, October 12-16, 2004.

the intended drug product shelf life, should also be demonstrated. The information on excipient performance can be used, as appropriate, to justify the choice and quality attributes of the excipient, and to support the justification of the drug product specification.

### 2.10.3. Physicochemical and biological properties

The physicochemical and biological properties relevant to the safety, performance or manufacturability of the drug product should be identified and discussed. This includes the physiological implications of drug substance and formulation attributes. Studies could include, for example, the development of a test for respirable fraction of an inhaled product. Similarly, information supporting the selection of dissolution vs. disintegration testing, or other means to assure drug release, and the development and suitability of the chosen test, could be provided in this section.

**Partial conclusion**

What was discussed and presented in chapter one which mainly defined concepts and theories, allows me to find out that the attraction of foreign investors in pharmaceutical Industries in East Africa is a very fundamental and essential issue for a deep discussion and merits special attention from various legal actors in international economic law, Business law and in full pharmaceutical industries across all Countries of East Africa. This is especially shown by the fact that the concept has its origin and some principles.

After dealing with general overview, by issuing some definitions related to the topic in different sources and to know how it is considered in East Africa, I am going to demonstrate the attraction of the foreign investors for pharmaceutical industries in Africa in chapter two which deals with a deep analysis on the attraction of the foreign investors for pharmaceutical industries in Africa especially in Rwandan business law.

# CHAPTER III: INVESTMENT PROMOTION AND FACILITATION UNDER KENYAN LAW

## 3.1. Promotion of investment in EAC states in general

To promote investment in the continent, the region and EAC the countries have, through the organization and Development Strategy set out the priority programmes for the continent focusing on macroeconomic cooperation; trade liberalization and development; cooperation in infrastructure; the development of human resources, sciences and technology; and cooperation in legal and judicial as well as political framework affairs.

Therefore, this chapter is made up some East African' Countries that tried their best to elaborate the incentives, facilitation and promotion of foreign investment in pharmaceutical industries under Policies and legal Compliance.

### 3.1.1. Country-Specific Challenges and Priority Intervention Areas

Each EAC Partner State has its own unique challenges and opportunities that influence its priorities for the pharmaceutical sector. All the EAC Partner States have established a national health sector policy, health sector strategic plans, a medicine policy and a relevant institutional framework (Ministry of Health, medicine regulation and procurement agency), as well as a national Essential Medicines List (EML) and regulations. Burundi and Rwanda, however, still have no autonomous medicines regulatory authorities in place. In Burundi, insufficient capacity of medical stores and inadequate supply and distribution chains are critical factors that need to

be addressed in the short term. This is also true for inefficient stock monitoring and procurement planning to prevent stock-outs in Uganda. All countries lack strategies to promote investment, access to finance, R&D capacities, technical expertise and qualified HR required for a local manufacturing upgrade. Country-specific challenges include

**A) In Kenya**

There is Insufficient access to credit for further upgrade of the sector, Insufficient R&D for the pharmaceutical sector development, Lack of comprehensive incentive packages including preferential procurement of locally produced medicines, Lack of stratification of knowledge and skills required in pharmaceutical sector, Inadequate policy and legislative framework for strengthening local manufacture of pharmaceuticals, Lack of information and ineffective monitoring of patented products , Weak collaboration between industry and academia in leveraging the benefits inherent in TRIPS flexibilities and Unclear attraction and retention strategies for direct foreign investment and local re-investment[129].

**B) In Tanzania**

There is insufficient incentive frameworks and financing schemes to support pharmaceutical investment:

Need to scale up and benefit from existing R&D, Strong competition from imports, High cost of upgrading and maintaining GMP, Lack of appropriate infrastructure, utilities and support systems, Lack of sufficiently skilled human resources, Inconsistent tax policies[130].

**C) In Uganda**

There is insufficient incentive frameworks and financing schemes to support pharmaceutical investment, Uganda is characterized by:

[129] Kenya Pharmaceutical Sector Development Strategy (2012)
[130] Tanzania Sustainable Industries Development Policy (1996–2020), Tanzania Integrated Industrial Development Strategy (2025). 100-134 P

Insufficient R&D for the pharmaceutical sector development, Lack of framework for interaction between industry, policy makers and regulation, Limited access to pharmaceutical inputs, raw materials and support services, Weak connection between industry, policy makers and regulation[131].

**D) In Burundi**

There are security constraints, in Burundi is characterized by:

No adequate regulatory framework for medicines, Lack of a national strategy for the pharmaceutical sector , Long registration timelines for pharmaceutical companies, Lack of sufficiently skilled personnel and knowledge in the pharmaceutical industry, High cost of production and transport , Inadequate national quality control and reference laboratory services, Lack of appropriate infrastructure, utilities and support systems , Inadequate policy and legislative framework for strengthening local manufacture of pharmaceuticals[132].

E) **In Rwanda** there is no autonomous medicine regulatory authority in place, Rwanda is characterized by:

High cost of production and transport, Lack of a strategy to promote investment, Limited access to finance, need to identify niche area across the pharmaceutical sector's value chain in the mid to long term, Lack of sufficiently skilled personnel and knowledge in the pharmaceutical industry and Lack of information on market size[133].

**F) In South Sudan** there is poor health commodities security (pharmaceuticals and equipment) South Sudan is characterized by:

No local production of pharmaceuticals, Inadequate and poorly managed pharmaceutical storage capacity and network across the country , Uncoordinated drug donations and parallel

[131] The Food and Drugs Act, Cap. 278, Laws of Uganda
[132] Burundi National Strategy for Industrial and Commercial Development: 2014¬–2020
[133] Rwanda National Pharmaceutical Policy (2016)

supply chain system, Inadequate national quality control and reference laboratory services, Low and progressively declining public sector health budget and difficulties in accessing the approved budget , Over-reliance on oil as the main source of revenue for government health financing , Limited legislative and regulatory capacity and Underdeveloped infrastructure poor road network and unreliable electricity supply.

And In DR Congo also some discussed challenges are manifested indeed, all Partner States face their own unique challenges in promoting local pharmaceutical production, which need to be articulated and prioritized within the wider framework of the regional plan[134].

### 3.2. Promotion of investment in pharmaceutical industries in Kenya

Kenya requires a coordinated approach and system to support the effective implementation of these laws and policies, and regularly evaluate the performance of public and private sector role players in the pharmaceutical industry value chain. Robust governance and timely sharing of reports with relevant agencies in government and with policymakers for Kenya presents a big market opportunity for locally manufactured pharmaceutical products. The country's trade treaties allow manufacturers to access other countries in the region. However, to drive and sustain the growth of the local pharmaceutical industry, these markets will need to be further developed. Further action will help ensure policies are implemented[135]. This is particularly important, as many of these laws and policies either fall within the mandate of different government ministries or are contradictory, and when implemented by individual government ministries, result in process-related tensions and delays in achieving desired outcomes[136].

The Ministry of Health and the Ministry of Industrialization, Trade and Enterprise Development are the two key ministries that are collaborating to realize Kenya's goal of

[134] African Development Bank, 2013, South Sudan: A Study on Competitiveness and Cross Border Trade with Neighboring Countries, 87P

[135] 2nd edition EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027

[136] EAC RPMPOA Regional Steering Committee Support the EAC Secretariat and Partner States in the implementation of the EACRPMPOA: 2017–2027. P. 7

becoming a regional hub for the manufacturing and distribution of pharmaceutical products. This partnership should be complemented by other ministries and agencies working to address issues relating to corrupt practices, unreliable utilities (water and electricity from the national grid) for industry, lack of certain specialized skills in the local workforce for pharmaceutical product development and manufacturing processes, and unnecessary complexity in tax regimens[137].

A comparative survey was conducted by pharmaceutical manufacturing companies to highlight the key attributes for attracting investment in Kenya's pharmaceutical industry. The aim was to identify and map the important factors or conditions that confer an advantage on countries and pharmaceutical manufacturing companies in the fight for market share locally and globally. Of the nine companies chosen for comparison, four were from Kenya and the other five from the peer countries of Bangladesh, Egypt, Ethiopia, and South Africa[138].

Locally manufactured medicines account for about 30 percent (in value) of market share in Kenya, while in Uganda and Tanzania, the share amounts to 20 percent and 12 percent, respectively. A Kenya pharmaceutical trade data report by Kenya's Pharmacy and Poisons Board (PPB) and a scoping study by the Clinton Access Initiative on the East African pharmaceutical market show that: Anti-infective and immunological and cardiovascular agents make up about 50 percent of the market share by value[139]. An estimated 66 percent of disease conditions are covered by locally produced medicines[140].

[137]. MoH (2009), National Health Policy (NHP)p.7

[138] abid

[139] Morgan, S. et al. (2008) 'Balancing health and industrial policy objectives in the pharmaceutical sector: lessons from Australia', Health Policy 87(2): 133–145.

[140] Registration of premises under the Pharmacy and Poisons Act (Cap. 244).pest control products

### 3.2.1. Innovation funds and increasing insurance coverage provides opportunities

The East African Health Research Commission was set up in 2015 with the mandate to promote and coordinate research and development activities in the region, including developing capacity in pharmaceutical research and development. A regional innovation fund has not been established, but each member state has set up its own national innovation fund. However, public sector debt rose to 58 percent of GDP in 2019, up from 41 percent in 2013, and became more no concessional (67 percent) than concessional[141]. The debt creates risks for refinancing, cost escalation, and foreign exchange. Due to Kenya's liquidity challenges, in 2018 the IMF raised the probability of Kenya's stress level from low to moderate[142].

### 3.2.2. The health sector and legal landscape

Kenya has a well-developed health sector that responds reasonably well to the country's needs. The health system is resilient and continually adapts to improve access to services for citizens. Legal, policy, and regulatory frameworks govern standards and practices in the sector. The current health sector landscape in Kenya is detailed below. The FBOs can be divided into three categories, the Kenyan Conference of Catholic Bishops, which has many Catholic mission hospitals. It currently has 453 health facilities, 18 medical training colleges (nursing, pharmacy, and clinical medicine), and more than 46 community-based health programs and orphans-and-vulnerable-children programs. The Christian Health Association of Kenya, a protestant membership-based organization, has about 507 health facilities spread across the country. The Supreme Council of Kenyan Muslims is the umbrella body of all Muslim organizations,

[141] 0 Kaplan W., Laing R, Local production of pharmaceuticals: industrial policy and access to medicines. World Bank HNP discussion paper. 2005, p 78

[142] World Intellectual Property Organization (1883). *Paris Convention for the Protection of Industrial Property*. In https://www.wipo.int/treaties/en/ip/paris/.

societies, and groups in Kenya[143]. It coordinates health activities and services provided by Islamic facilities and institutions[144].

### 3.2.3. The health system

Health is enshrined as a right under the Kenya Constitution 2010, and the government has committed enormous resources every year to fulfil its promise to improve citizens' access to quality services. The Constitution and health sector envision a healthy, productive, and globally competitive nation through building a progressive, responsive, and sustainable health-care system for accelerated attainment of the highest standard of health for all citizens. The sector is led by the Cabinet Secretary for Health at the national level, who is responsible for health policy, health regulation, national referral health facilities, capacity building, and technical assistance to counties[145]. The Health Sector Partnership Coordination Framework guides engagements between the Ministry of Health, county governments, and external and no state partners[146].

A resilient health system is one that continually seeks to improve the quality of its products and services and the sustainability and efficiency of commodity procurement and delivery. In general, strengthening a health system should involve developing sound legal frameworks to ensure public trust; building information systems to monitor performance, assess quality, and align incentives to outcomes; improving early-warning mechanisms for disease outbreaks and natural disasters; and developing processes for systematic reduction and containment of national and global health risks. Since devolution in 2013, Kenya's public health sector has

[143] Murugi, B.M. et al. (2010) Strengthening pharmaceutical innovation in Africa, Council on Health Research for Development (COHRED)/New Partnership for Africa's Development (NEPAD).
[144] World Health Organization (2005). *Remuneration guidelines for non-voluntary use of a patent on medical technologies*. In https://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf.
[145] The EAC Industrialisation Policy: 2012–2032
[146] abid

been run by the national government and the 47 county governments[147]. The national government is responsible for health-care service delivery at the Level 6 national teaching and referral hospitals (Kenyatta National Hospital, Moil Teaching and Referral Hospital, National Spinal Injury Hospital, and the Mathai Teaching and Referral Hospital)[148]. The counties are responsible for providing Level 1 to Level 5 services, such as county referral, primary care, and community health[149].

The private sector consists of for-profit commercial players and not-for-profit players such as faith-based organizations (FBOs) and nongovernmental organizations (NGOs). The private sector dominates the nursing home segment and health clinics. The public sector and FBO/NGO sectors own most of the health centres and dispensaries in the country and the governance of private insurance companies. Financing mechanisms have been introduced to reduce the burden on poor and vulnerable groups. Examples include abolishing user fees at public health facilities, free maternity services, lease of medical equipment, and the Health Insurance Subsidy Programme for the poor[150]. The NHIF has employed mobile technology, such as USSD (unstructured supplementary service data) and apps, to increase enrolment and ease of premium payments[151]. The NHIF has also broadened the benefits package, which now includes outpatient services, cover for chronic diseases such as cancer, diabetes, and hypertension, and increased access to small and medium-sized private sector health facilities[152].

[147] Shadlen, K. and da Fonseca, E. (2013) 'Health policy as industrial policy: EAC in comparative perspective', Politics and Society 41(4): 561–587.
[148] Global Atlas of the Health Workforce. WHO, Geneva, 2006
[149] Ukraine. Economic Court of Kyiv. (2018). *Judgment in case n° 910/4881/18.* Inhttps://verdictum.ligazakon.net/document/78650682.
[150] Reichman, J.H. (2009) 'Compulsory licensing of patented pharmaceutical inventions: evaluating the options', Journal of Law, Medicine & Ethics 37(2): 247–263.
[151] Mytelka L K; Pathways and policies to (Bio) Pharmaceutical Innovation Systems in Developing Countries, Innovation and Industry; December 2006.
[152] Licence for a sterilizing plant under the Fertilizers and Animal Foodstuffs Act(Cap. 345).

### 3.2.4. Increased investment in health-care infrastructure

In 2018, the number of health facilities in Kenya grew by 10 percent to 10,820, while registered health personnel increased by 6.3 percent to 175,681[153]. The number of middle-level medical graduates from public medical training colleges increased by 21.2 percent to 10,869, while medical undergraduates and postgraduates were expected to increase by 6.0 percent to 4,470 in the 2018/19 academic year[154].

### 3.2.5. Health workforce

There are eight health regulatory agencies established through acts of parliament to help govern the sector. These include:

- Nursing Council of Kenya
- Medical Practitioners and Dentist Board
- Clinical Officers Council
- Kenya Medical Laboratory Technicians and Technologists Board
- Pharmacy and Poisons Board
- Public Health Officers and Technicians Council
- Radiation Protection Board and Kenya Nutritionists and Dieticians Institute. Registration

of health professionals across cadres has increased consistently, with the exception of pharmacists, whose numbers have varied[155]. There is a huge disparity in health workforce distribution across the country, influenced by demographics, number of health-care facilities, and the epidemiological profile of individual counties[156].

[153] Ggombe, K., & Newfarmer, R. (2017, April). Rwanda: From devastation to services-first transformation. Retrieved from https://www.wider.unu.edu/sites/default/files/wp2017-84_0.pdf
[154] abid
[155] Kenya GMP Roadmap, A Stepwise Approach for the Pharmaceutical Industry to Attain WHO GMP Standards, 2014. 107
[156] The World Bank. https://www.worldbank.org/en/region/afr/overview.

### 3.2.6. Long-term strategy and Technology transfer

East Africa can explore technology transfer agreements to access vaccines. Since vaccine production is more complicated than manufacturing other pharmaceutical products, know-how is more important than intellectual property. In the past, technology transfers have led to an improvement in the accessibility and affordability of key vaccines for developing countries. For example, when the hepatitis B vaccine was introduced in industrialized countries in 1983 it cost $100 per dose[157]. In the late 1990s, after the technology transfer to the Republic of Korea, India, and Brazil, the price dropped to between $5 and $7 per dose, and this was reduced further as a consequence of financial assistance from Gavi and purchasing entities[158]. As a result, the vaccine became more accessible and was included in most national immunization programs. India is one country that has benefitted greatly from technology transfers[159].

According to a WHO report, between 1988 and 2010, East Africa received the most technologies through technology transfers. Traditionally, technologies have been transferred through bilateral agreements, joint ventures, or acquisitions. However, a new trend is the emergence of technology transfer hubs through which several manufacturers are able to receive the technology simultaneously[160]. Examples include the NVI Influenza hub in the Netherlands in which 15 researchers/manufacturers received technology transfer, and a technology hub at the University of Lausanne in Switzerland[161].

According to WHO, the cost of manufacturing vaccines in Brazil, India, and China is increasing, while an increasing number of members of the Developing Countries Vaccine

[157] Sylvester Rugumambaju and Paul Kutyabami, 2010. Pharmaceutical Sector Profile: Uganda. United Nations Industrial Development Organisation (UNIDO), Vienna.
[158] PAN AFRICAN EXPERTS MEETING ON ACCESS TO AND RATIONAL USE OF MEDICINES organized by Health Action International, HAI-Africa in collaboration with the Ecumenical Pharmaceutical Network. 14, 15 November 2007, Nairobi, Kenya
[159] Tomarov, I. (2020). Covid-19, respirators and patents for industrial designs. Vasyl Kisil Law Firm. In https://vkp.ua/ua/publication/covid-aparati-shtuchnogodikhannya- ta-patenti-na-promislovi-zrazki.
[160] Riviere., J.E. and Buckley, G.J. (2012) Ensuring safe foods and medical products through stronger regulatory systems abroad, National Academies Press, Tanzania.
[161] abid

Manufacturers Network are ready to transfer technology, which should make the transaction cost of technology transfer lower.

For countries to successfully develop vaccine manufacturing capabilities, a well-established vaccine policy may assist in identifying when and how to consider local production[162].

### 3.2.7. Immunization in

Between 2000 and 2019, Tanzania received more than $500 million from Gavi, the vaccine alliance, for vaccine co-financing, health system strengthening, and vaccine campaigns. This support is expected to decline, with Tanzania entering the accelerated phase of Gavi transition in 2022[163]. Under this arrangement, Tanzania will be expected to use its own resources to finance a higher proportion of vaccines currently funded by Gavi[164].

According to WHO, the cost of the routine immunization programme interventions is mainly financed by Gavi, followed by the national government. In 2014, Gavi contributed 71 percent of the total resources required to cover routine immunization, while the government contributed 24 percent and other development partners about 3 percent[165]. The total cost of routine immunization interventions was $75 million, with supplemental immunization activities constituting $28 million of this amount and underused vaccines another $25 million[166].

### 3.2.8. Insurance organizations

Health insurance in Kenya is provided by both public and private organizations. The NHIF is Kenya's national health insurance and has recently taken steps to expand its membership base. Membership of the NHIF is a statutory requirement for all employers and employees in the

[162] abid
[163] The Health of the People: the African Regional Health Report http://whqlibdoc.who.int/afro/2006/9290231033_eng.pdf
[164] Restaurant manager's licence under the Hotels and Restaurants Act (Cap.494) for the person specified in the investment certificate.
[165] Restaurant licence under the Hotels and Restaurants Act (Cap. 494).
[166] abid

formal sector and is optional for others. Over the past five years, via the Health Insurance Subsidy Programme and Supa Cover, efforts have been made to strengthen the membership base in the indigent and informal sectors respectively. This has borne fruit, and membership in the informal sector currently stands at 4 million, making total membership of the NHIF about 7 million people or 35 percent of the population. Regulated by the Insurance Regulatory Authority, private insurance covers 2 percent of the population. Jubilee Insurance has the largest market share at 26 percent, followed by AAR Insurance at 17 percent and UAP at 14 percent. Micro insurance is growing and leverages the mobile money penetration in Kenya for convenient and affordable health services and medication insurance cover., in 2020 about 1.5 million Kenyans are covered by private health-care insurance[167]. In total, there are about 15 to 20 companies that provide health insurance cover[168].

### 3.3. 1. Increased interest from pharmaceutical companies

International pharmaceutical companies are showing increased interest in setting up their manufacturing plants or expanding their footprint in Kenya. For example, Square Pharmaceuticals from Bangladesh is setting up a manufacturing plant in one of Kenya's export processing zones (EPZs) to grow its regional reach and meet imported, despite attracting custom tariffs. Large and small pharmaceutical firms import about 60 percent and 35 percent of their packaging materials, respectively[169]. The industry also imports the machinery and equipment for production from Europe and Asia, including the specialized labour for equipment installation, maintenance, and repair services[170]. There is also a perception among pharmaceutical manufacturers that local packaging material is low quality[171].

[167] https://www.who.int/phi/publications/Cuba_case_study121115.

[168] The Lancet (2019). *The global burden of disease health financing collaborator network, past, present, and future of global health financing, 1995-2050*. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-67.

[169] Sarah Vugigi;Wilberforce Wanyanga; Frankline K. Keter,pharamaceutical industrial 300-367

[170] Brill, A., 2020. The Cost of Brand Drug Product Hopping, Washington, DC: Matrix Global Advisors.

[171] PricewaterhouseCoopers (2019). "Global Pharma & life sciences deals insights year-end 2019". PWC US. Available at:https://www.pwc.com/us/en/ industries/health-industries/library/pharma-life-sciences-quarterly-deals-insights.html.

### 3.3.2. Concentrated pharmaceutical manufacturing focused on limited drug types

Production of medicines by the pharmaceutical sector in Kenya is concentrated and dominated mostly by family-run businesses that focus on the simplest types of manufacturing,

The Kenyan pharmaceutical sector has not yet moved towards the most complex activities of the value chain. Most companies still manufacture simple no patented products or rely on technology transfer agreements with foreign multinational manufacturers. Three companies produce raw materials (e.g., raw Artemether base) for API production, but these materials are destined for export, as the local capacity for processing raw inputs into APIs is underdeveloped. Most packaging materials are also imported, despite attracting custom tariffs. Large and small pharmaceutical firms import about 60 percent and 35 percent of their packaging materials, respectively[172]. The industry also imports the machinery and equipment for production from Europe and Asia, including the specialized labour for equipment installation, maintenance, and repair services[173]. There is also a perception among pharmaceutical manufacturers that local packaging material is low quality[174].

Various types of pharmacies were surveyed, such as pharmacies in high-end clinics, single pharmacies in high-end areas, single pharmacies in medium-income areas, pharmacies in low-end clinics, and pharmacies in low-income areas. The objective was to understand the variations in price to consumers and mark-ups applied by pharmacies across different types of drugs (high priority/essential medicines, drugs which are exclusively imported, and drugs which are both manufactured in Kenya and imported). Field staff visited the pharmacies to fill out the survey[175]. The survey consisted of a table to be filled out for 30 products[176]. For each

[172] stores, inspection and substandard pharmaceutical products,2021, 320–321p
[173] Woodward, Douglas, and Robert Rolfe. "The Location of Export-Oriented Foreign Direct Investment in the Caribbean Basin." Journal of International Business Studies 24:1 (1993): 121–144.
[174] Registration as a grower under the Sisal Act (Cap.341). Condition: That the particulars required under the Sisal Industry (Registration) Rules be submitted within six months after the issue of the investment certificate.
[175] US Pharmacopeia, 32nd ed. General chapters: Analytical instrument qualifi cation. Rockville, MD, 2009.
[176] World Bank. The East Asian Miracle: Economic Growth and Public Policy. New York: Oxford University Press, February 1994 (First printing 1993)

product, data needed to be provided on brand name, name of manufacturing company, dosage form/strength/ pack size, price to the consumer, and mark-up[177].

### 3.3.3. The role of manufacturers

Many local pharmaceutical manufacturers in Kenya have found it challenging to meet GMP requirements. Some of the challenges they face relate to the physical site and the quality management system (QMS)[178]. For example, if the entity is renting space, it is difficult to modify the space without breaking the lease agreement or undermining the structural integrity of the building. Many manufacturers struggle to access capital from local banks to buy additional equipment and to expand and upgrade their infrastructure[179]. They suggest that the limited access to financing could be due to banks' reluctance to provide loans to an industry mostly dependent on perceived risky business, especially those dependent on public sector tenders with uncertain payment periods[180].

According to the IMF, access to capital was not an issue from 2007 to 2013. This changed with the introduction of (now repealed) interest rate controls in 2016. MEDS also encourages manufacturers to achieve high-quality standards by auditing manufacturers' sites and validating the quality of commodities. It uses its quality control laboratory to validate the quality of commodities it procures for distribution from local manufacturers[181]. The organization works with seven local manufacturers, and except for issues related to packaging, none of the products it has tested has failed on the drug quality parameters[182].

---

[177] abid

[178] Offi cial Medicines Control Laboratories Network of the Council of Europe, Quality Assurance Documents: PA/PH/OMCL (07) 28 p

[179] Stiglitz, J. E. (2009). Trade agreements and health in developing countries. The Lancet, 373/9661, 363-365

[180] Zaliska, O.M. & Stasiv, H.-O. I. (2019). "Managed access agreements" for innovative medicines to ensure the availability of drugs in European countries. *Apteka*. In https://www.apteka.ua/article/500494.

[181] RDB, why invest in Rwanda Available at http://www.rdb.rw/ departments /investment. html last on 22th September 2014

[182] X, Investment policy in Tanzania, available at http://wwwcutsccier.org/pdf/ InvestmentPolicyinTanzania%E2%80%93Performance and_Perceptions.pdf

More needs to be done by the national regulatory agencies to improve the quality of commodities in the market in Kenya to both protect consumers and achieve better treatment outcomes. For example, government could provide incentives to companies that are GMP compliant. To address knowledge gaps, the pharmaceutical industry could design and introduce short-term and long-term professional courses in collaboration with academia and regulators[183]. This will lead to increased awareness of GMP and increased industry capacity to enhance its quality control systems[184].

### 3.3.4. Distribution and retail trade

Distribution and selling of medical products are essential parts of the value chain in the supply of goods and services. Regulating the distribution and retail trade ensures that the quality of commodities in the supply chain is maintained, that accountable and fair practices are adhered to, and that illegal activity does not undermine access to health services[185].

The PPB is responsible for regulating the distribution and retail of pharmaceutical products in Kenya. It registers distributors, retail pharmacies, and pharmacists who apply and meet the set standards to conduct business in the pharmaceutical products value chain. All distributors and retail pharmacies are expected to be certified by the PPB to operate. However, Kenya's distribution and retail market is highly fragmented and not well regulated[186]. Despite there being a high number of licensed retail pharmacies, there are also many unlicensed ones that compete with the legitimate ones in the same market space[187]. The PPB inspects the premises of those involved in trade and takes action against those that do not comply with set standards,

[183] Pharmaceutical Preparations. Fortieth report. Geneva, World Health Organization, 2006, Annex 4, Appendix 4 (WHO Technical Report Series, No. 937).
[184] International Monetary Fund (2020). "IMF DataMapper: Real GDP growth". Available at: https://www.imf.org/external/datamapper/NGDP_RPCH@ WEO/OEMDC/ADVEC/WEOWORLD/AFQ (accessed June 30, 2020).
[185] abid
[186] International Society for Pharmaceutical Engineering, 2005, 421p
[187] U.S Department of Diplomacy in Action, 2014 Investment Climate Statement – Tanzania, Bureau of Economic and Business Affairs March 2013 Report.

but it has insufficient capacity to effectively regulate pharmacy trade and practice in Kenya[188]. All retail pharmacies are required by law to have a premise license and a qualified superintendent pharmacist licensed by the PPB. However, the full enforcement of this law remains a challenge in the country. The USAID's 2019 Kenya Health Assessment report estimates that there are about 6,000 unregistered pharmacies in Kenya[189]. Most of these unlicensed retail pharmacies obtain their supplies from redistributors and wholesalers[190].

Data on file from the PPB paints a different picture of the number of unregistered pharmacies in the country. Based on the PPB's survey of 5,672 retail pharmacies conducted between July 2019 and June 2020, 20 percent of pharmacies did not comply with the Good Distribution Practices. Although this sample did not cover all the pharmacies in the country, it is recommended that the PPB assesses/ surveys all the pharmacies and retail outlets to validate their registration and practice[191]. This would go a long way to provide the necessary evidence for decision making and strengthen the country's efforts to improve practice standards and the quality of drugs in the supply chain[192].

There is also a need to strengthen the capacity of the PPB and other complementing agencies to enforce practice standards and regulations. The full implementation of the Joint Health Inspection Checklist, gazetted on March 21, 2016, was expected to help further regulate retail pharmacy trade and practice. The checklist will require regular audits of all public and private

---

[188] African Development Bank Group (2020). African Economic Outlook 2020. Available at: https://www.afdb.org/en/knowledge/publications/african-economic-outlook (accessed June 30, 2020).

[189] Kenya Pharmaceutical Sector Development Strategy (2012)

[190] Africa Development Bank Group (2020). "African Economic Outlook 2020". Available at: https://www.afdb.org/en/news-keywords/african-economic-outlook 2020#:~:text=The%202020%20African%20Economic%20Outlook,2020%20and%204.1%25%20in%202021.

[191] World Health Organization, 2002, Annex 10 (WHO Technical Report Series, No. 902).

[192] Qiang, C.Z., Yamamichi, M., Hausman, V., Miller, R. (2012). *Mobile applications for the health sector*. Washington, D.C.: World Bank Group. Available at: https://documents.worldbank.org/en/publication/documents-reports/documentdetail/751411468157784302/mobile-applications-for-the-health-sector.

health facilities (including retail pharmacies). Those that meet the required standards will be certified, while those that do not will be closed[193].

### 3.3.5. Exports

The process of exporting medicines from Kenya is similar to that of importing them into the country but in reverse. However, there are additional requirements in the destination country:
A preferential certificate of origin is granted by the Kenya Revenue Authority for exports destined for countries that have a trade agreement with Kenya[194].

A non-preferential certificate of origin is granted by the Kenya National Chamber of Commerce and Industry for exports destined for countries without a trade agreement with Kenya. Additional formalities (registering with the appropriate local authority and payments) are required in the destination country in the absence of a harmonized system. However, according to the PPB, the harmonization process is under way in the East African region. Joint registration will be recognized in East Africa. This will be supported by a common technical document for South Sudan, Tanzania Mainland, Kenya, Uganda, Burundi, Rwanda, and Zanzibar[195].

Eventually, regulators plan to cross-recognize inspections undertaken and reports issued by peers in any of the member countries. A respondent in the pharmaceutical manufacturing industry reported that Ethiopia and Tanzania take much longer than other countries to register products from Kenya. Products locally manufactured and in use in Kenya face few challenges in obtaining registration in Uganda and Djibouti. Several bodies oversee function and practice in Kenya's pharmaceutical industry. Some of them fall under the Ministry of Health, while

[193] ibid
[194] The Kenyan Investment Act, No. 26 of 1997 to promote, co-ordinate and facilitate investment
[195] The Embassy of united States Kigali-Rwanda, 2013 Investment Climate Report, available at http://rwanda.usembassy.gov/investment_climate html,last access 12th May 2014

others report to other ministries[196]. Bodies that oversee IP matters, manufacturing and practice licensing, quality assurance, taxation, and environmental to attract, promote, protect and facilitate foreign investors in field of pharmaceutical industries in Kanya[197].

## CHAPTER IV: THE ATTRACTION OF FOREIGN INVESTMENTS FOR PHARMACEUTICAL INDUSTRIES UNDER RWANDAN LAW

The adoption of the new Constitution revised in 2023, by referendum paved the way for the first post-genocide legislative and presidential elections, and represented a further step towards entrenching peace and stability. The Constitution provides in its article 12 a framework for the fundamental individual rights expected in a modern democracy and establishes a multiparty system for the first time in Rwanda since independence, with the exception of a doomed attempt to introduce democracy with the 1991 Constitution[198]. The Constitution, aside from the usual separation of executive, judiciary and legislative powers, puts in place a number of mechanisms that seek to deal with the article 12 of Rwandan Constitution of 2003 revised in 2023 stipulates the Right to life everyone has the right to life, therefore in the special incentives, the pharmaceutical industries must be included as fundamental facilities to human being for the safe guard of the life. No one shall be arbitrarily deprived of life[199].

### 4.1. Priority economic sectors

Article 4 of the law n° 006/2021 of 05/02/2021 on investment promotion and facilitation, sets out the priority economic sectors that benefit from investment incentives as following:

1º export;

[196] Medical Laboratory Technicians and Technologists Act (1999)

[197] Canada. Supreme Court. (2017). *AstraZeneca Canada Inc. v. Apotex Inc.: Judgment*. In https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/16713/index.do.

[198] constitution of the republic of Rwanda revised in 2023 in its article 12, stipulates the right to life

[199] Article 21, of the Rwandan Constitution Revised in 2023

2º manufacturing in the textiles and apparel, electronics, information communication and technology equipment, large scale agricultural operations excluding coffee and tea, pharmaceuticals, processing in wood, glass and ceramics, processing and value addition in mining, agricultural equipment and other related industries that fall in these categories;

3º energy generation, transmission and distribution;

4º information and communication technologies, business process outsourcing and financial services;

5º mining activities relating to mineral exploration;

6º transport, logistics and electric mobility;

7º construction or operations of specialised innovation parks or specialised industrial parks;

8º affordable housing;

9º tourism that includes hotels, adventure tourism and agro-tourism;

10º horticulture and cultivation of other high-value plants included on the list approved by the Board;

11º Creative arts in the subsector of the film industry;

12º Skills development in areas where the country has limited skills and capacity as determined by the Board[200].

This provides that an international company which has its headquarters or regional office in Rwanda will be entitled to a preferential corporate income tax rate of zero per cent (0%) if it fulfils the following requirements

To invest the equivalent of at least ten million United States Dollars (USD 10,000,000), in both tangible or intangible assets, in Rwanda;

To provide employment and training to Rwandans

[200] article 4, of the law n° 006/2021 of 05/02/2021 on investment promotion and facilitation

To conduct international financial transactions equivalent to at least five million United States Dollars (USD 5,000,000) a year for commercial operations through a licensed commercial bank in Rwanda[201];

To be well established in the sector within which it operates;

To use the equivalent of at least two million United States Dollars (USD 2,000,000) per year in Rwanda;

To set up actual and effective administration and coordination of operations in Rwanda and perform at least three (3) of the following services in Rwanda

Procurement of raw materials, components or finished products;

Market control and sales promotion planning;

Information and data management services;

Treasury management services;

Research and development work;

Training and personnel management[202] In accordance with the article 12 of Rwandan Constitution of 2003 revised in 2015 and in accordance with the article 4 of law n° 006/2021 of 05/02/2021 on investment promotion and facilitation paragraph 2, the special there should be the pharmaceutical industries or services because the Rwandan Constitution specified that everyone has the right to life, therefore one cannot say right to life without saying the opportunities of being facilitated, protected and promoted each and every thing that may help everyone to obtain medicaments, health treatment and health care felicities in all corners of life[203].

[201] Special incentives on the Investment Law 08/02/2021, the annex of the law n° 006/2021 of 05/02/2021 on investment promotion and facilitation

[202] Special incentives on the Investment Law 08/02/2021, the annex of the law n° 006/2021 of 05/02/2021 on investment promotion and facilitation

[203] article 12 of Rwandan Constitution of 2003 revised in 2015

### 4.2.1. Preferential with holding

A preferential withholding tax of zero per cent (0%) is applicable to dividends, interest and royalties paid by investors benefiting from preferential corporate income tax of 15% and 3%

A preferential withholding tax of 5% is applicable to dividends and interest income paid to an investor investing in a company listed on the Rwanda Stock Exchange

A preferential withholding tax of 10% is applicable to specialized innovation park developers or specialized industrial park developers on interest on foreign loans, dividends, royalties, and a service fee, including management and technical service[204]

### 4.2.2. Export Incentives

Investors exporting goods and services are granted the following preferential income taxes:

The 25% of CIT is reduced if at least 30% of total turnover of goods and services and is less than 50% of total turnover comes from export. (Applicable for the first 5 year of achieving 30%)

The of 15% corporate income tax if at least 50% of total turnover comes from export registered investor investing in products used in export processing zones is exempted from customs taxes and duties in accordance with provisions of the East African Community Customs Management Act. A small and medium investor or emerging investor is entitled to 150% tax deduction of all qualifying expenditures relating to internationalization; overseas marketing

Participation in overseas trade fairs not supported by another existing initiative

Overseas business development costs market entry and research costs such as costs of establishing a legal entity in a foreign market, salary costs of employees stationed in foreign market, analysis of market opportunities, supply chain and entry requirements. Pre-approval by RRA & MINICOM is required and claim should not exceed $100M[205]

[204] article 4 of law n° 006/2021 of 05/02/2021 on investment promotion and facilitation paragraph 2
[205] Official Gazette n° 04 bis of 08/02/2021

### 4.2.3. Philanthropic investors Incentives

A preferential income tax of 0% upon the approval of the philanthropic investor by the Private Investment committee. VAT and CIT exemption on funds transferred to the entity for the purposes of financing its social impact activities. Employment income tax exemption to foreigners residing in Rwanda provided they do not exceed 30% of the professional staff. Refund of Paid social security contributions to foreign staff upon permanent departure from Rwanda[206].

### 4.2.4. Innovation parks & Industrial parks incentives

5-year property tax exemption for developers of specialized innovation park or special industrial park, land transfer fee exemption if the transferor holds shares equivalent to the value of immovable properties, carry forward accumulated tax losses in the event of a change of ownership of share capital or voting rights amounting to 25% in a given year if;

change of ownership occurs during the construction phase prior to the asset being operationalized and generating revenue, first change of ownership of share capital or voting rights amounting to more than twenty-five per cent (25%) in a given tax period upon operationalization of the asset. Subsequent changes of ownership of share capital or voting rights amounting to more than twenty-five per cent (25%) do not benefit from this incentive.

carry forward losses for a period of seven (7) years from the first year of making the loss, by deducting losses in the order in which they incurred. After this period, the developer may request the Tax Administration for an extension in accordance with the relevant laws

50% accelerated depreciation in respect of capital expenditures incurred for a period of one (1) year from the date on which construction works were started

[206] ibid

Expedited pre approval and value added tax refunds for professional and technical services procured outside Rwanda

0% VAT for construction materials and finished goods at investment for construction projects within specialized innovation parks or specialized industrial parks.

Domestic taxes (withholding tax and excise duty) exemption if applicable, on importation of construction materials and finished goods.

### 4.2.6. Industry Incentives for foreign investor who start up

a) With the exception to the capital funds, foreign investors investing a maximum of $500 **start-up** are eligible for
b) Exemption from withholding tax applicable to dividends paid for five (5) dividend issuances by the start-up.
c) Investment to remain in the startup for at least 2 years.
d) The Seed Innovation Fund provides a variety of instruments including convertible grants, equity and debt for the following qualifying activities
e) qualifying manpower costs
f) Training costs
g) Costs for materials, equipment, software and technology acquisition;
h) Professional services engaged
i) Costs incurred on intellectual property rights[207].

A registered film investor is entitled to the following incentives;

Zero rated VAT for goods and services procured locally

[207] The whole annex of the law n° 006/2021 of 05/02/2021 on investment promotion and facilitation

Zero rated Withholding Tax to foreign specialized services procured by the investor. A list of the qualifying foreign specialized services is jointly approved by the Rwanda Film Office and the Rwanda Revenue Authority[208].

### 4.2.7. Attraction Incentives

Entrepreneurship visa for Start-up founders and innovative entrepreneurs who are foreigners and their dependents to start business in Rwanda in accordance with relevant laws, talent visa for Qualifying international students from qualifying higher institutions of learning commencing from the date of completion of their studies[209].

Qualifying remote workers in priority professional fields are eligible for a 2year visa allowing them to live in Rwanda and legally work for an employer registered abroad or their own company. The eligibility criteria are determined by relevant laws.

Company, which has established its headquarters or regional office in Rwanda, is entitled to recruit any required managerial, professional and technical foreign employees who will be eligible to be issued with work permits if they meet the following requirements:

The company is a talent intensive business operating in a high value sectors such as information and communication and technology, innovation and related sectors, at least thirty per cent (30%) of the company's professional staff are Rwandan. Visas to be issued in line with talent attraction incentives are processed in a period not exceeding 2 weeks. High net worth individuals are eligible to be granted permanent residence status upon fulfilling eligibility criteria determined by the relevant laws. High net worth individuals may also be granted Rwandan nationality by acquisition upon application following five (5) years from the date of receipt of permanent residence status, and if they continue to meet any of the requirements of

[208] abid
[209] article 14, 16: law n° 006/2021 of 05/02/2021 on investment promotion and facilitation, and xxi

this category as follows[210]. To invest at least one million United States Dollars (USD 1,000,000) in an investment activity in Rwanda to own a luxury property in Rwanda valued at least five hundred thousand United States Dollars (500,000 USD).

### 4.2.9. Non-Fiscal Incentives

Upon fulfilling all tax obligations in Rwanda, an investor shall be allowed to repatriate the following:

a) Capital; profits derived from business activities; debt and interest on foreign loans; proceeds from the liquidation of investment
b) Any other assets of an investor

Quick business and investment online registration, assistance with tax-related services and exemptions, assistance with access to utilities (water & electricity), assistance with obtaining visas and work permits, one stop Centre that provides notary services, migration, Provision of aftercare services to fast-track project implementation, regardless of the origin of investor, all business sectors are open to private investment[211]. As it is mentioned from (4.2.1) to (4.2.9) in special incentives set out in the annex of the law n° 006/2021 of 05/02/2021 on investment promotion and facilitation, in its article 06, which annex of the Official Gazette n° 04 *bis* of 08/02/2021, in which the Pharmaceutical Industries was not included which means that it was not followed the article 12 of the Rwandan Constitution of 2003 revised in 2015, where it is granting to everyone the right to life, thus Rwanda development Board (RDB) did focus on this, that makes a gap in attracting foreign investors in pharmaceutical industries under Rwandan Policies and legal Compliance[212].v

[210] ibid
[211] Rwanda National Pharmaceutical Policy (2018)
[212] Rwandan Law n° 26/2005 of 17/12/2005 relating to investment and export promotion and facilitation

### 4.3. Opportunities of Pharmaceutical Industries in Rwanda

Even though, there is no industry that produces medicines, Rwanda has three stores in charges of storing pharmaceutical products such as BUMAR which is the Bureau of medical training adopted in Rwanda, as NGO, created in 1975 by the confessions for Christian working in RWANDA who are expert in field of health. BUFMAR has mission of contributing to all human being in Rwanda by providing the quality disposition of health services for them[213].

MEDISOL was Established in 2009, it is the leading supplier in Laboratory Supplies in Rwanda and MDS, the Rwanda Medical Supply Limited is a large-scale corporation created and owned by the Government of Rwanda. RMS ltd objective is to ensure availability of medicines, medical supplies and consumables in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to the Rwandan population. This should be achieved by controlling the medicines supply chain in the territory of Rwanda. Rwanda Medical Supply Limited (RMS Ltd) has full financial, legal and administrative autonomous[214].

It is procuring, storing and distributing drugs, medical supplies and consumable to be used in all public health facilities[215]. The economy of scales is also another factor that can push the cost to be maintained as low as possible[216].Apart from these three companies in charge of pharmaceutical products in Rwanda, in August 2021, BioNTech agreed to set up vaccine production capabilities in Africa together with the KENUP Foundation in Rwanda[217]. The

[213] Annual Report of Ministry of health, 2012
[214] Progress health indicators report 2012, 101-120p
[215] Rwanda MoE. (2010). Education Sector Strategic Plan. Ministry of Education: Kigali, Rwanda
[216] Rwanda Health Sector Policy (2015).
[217] EAC, African Development bank and African Development Fund, East African Community (EAC) investment Guidebook, 2013, 79-81 p

decision was guided by the African Union, the Africa Centers for Disease Control and Prevention (Africa CDC), and the African Medical Agency under formation[218].

Germany-based biotechnology company BioNTech had built its first modular mRNA vaccine manufacturing facility in Kigali, Rwanda, to promote sustainable vaccine production and end-to-end vaccine supply in African Union member states. The facility will manufacture mRNA vaccines as part of its malaria and tuberculosis vaccine development programmes[219]. It will serve as a confluence point in a decentralised, robust network of end-to-end manufacturing in Africa[220].

[218] Rwanda National Industrial Policy (2011)
[219] Health Records and Information Managers Act (No. 15 of 2016)
[220] Danish Association of the Pharmaceutical Industry. Note on Pharmaceutical Expenditure, 48-56 p

# CHAPTER V: CONCLUSION AND RECOMMENDATIONS

## CONCLUSION

Drawing a general conclusion on Rwanda's legal system regarding incentives for pharmaceutical industries compared to Kenya requires a nuanced assessment of both countries' legal frameworks and policies. Here are some general points to consider

As Rwanda, there should be investment-Friendly Environment where Rwanda has made efforts to create an investment-friendly environment, including incentives for various industries, including pharmaceuticals. The country has a single-window system to streamline business registration and reduce bureaucratic hurdles.

There should be access to Markets where Rwanda is part of the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA), providing pharmaceutical companies access to larger markets. Additionally, Rwanda is known for its focus on regional integration and trade facilitation, therefore this should be a great opportunity to attract foreign investment in pharmaceutical industries.

The Local Pharmaceutical Manufacturing where Rwanda has made investments in local pharmaceutical manufacturing, aiming to reduce reliance on imports. This includes initiatives to support local production of essential medicines. But it should be better where foreign investors are facilitated and attracted to invest in pharmaceutical industries especially in local

pharmaceutical industries so that the Rwandan market on pharmaceutical product be efficient and produces many products as enough.

As Rwandan Regulatory Framework for pharmaceuticals is governed by the Rwanda Food and Drugs Authority (FDA), which oversees drug registration, quality control, and safety standards, this should be increase the effort in encouraging the foreign and create the special incentives as tools attracting foreign investments in pharmaceutical industries.

As Kenya there is an established Industry, where Kenya has a well-established pharmaceutical industry with numerous manufacturers and a strong presence in the East African region. It benefits from economies of scale and a large domestic market.

As Trade Agreements, in Kenya's membership in trade agreements such as the African Continental Free Trade Area (AfCFTA) and the East African Community (EAC) offers opportunities for market access and export, therefore Kenya benefit from it, and get much income from pharmaceutical industries.

Investment Incentives, in Kenya has implemented various investment incentives, including tax benefits and export processing zones, which can benefit the pharmaceutical sectors the foreigner investors included.

Regulatory Framework, in Kenya's pharmaceutical sector is regulated by the Pharmacy and Poisons Board (PPB), which oversees drug registration, quality control, and compliance with international standards, in this board rules there are special incentives attracting foreigner investors in pharmaceutical industries.

Finally, I conclude that in regarding the incentives for pharmaceutical industries in Rwanda compared to Kenya depends on various factors, including the specific needs and goals of pharmaceutical companies. Both countries have taken steps to encourage investment in the

sector, but Kenya's more established industry, larger market, and historical advantages provide certain advantages for pharmaceutical industries rather than Rwanda.

However, Rwanda's smaller and more focused market, along with its emphasis on regulatory compliance and regional integration, may be attractive for foreign investments targeting specific niches or seeking a strategic regional foothold in pharmaceutical industries.

Ultimately, the choice between Rwanda and Kenya as a destination for pharmaceutical industry investment would depend on pharmaceutical business model, target markets, and long-term objectives. It's advisable for Rwandan to conduct a thorough analysis, consider regulatory requirements, and engage with relevant stakeholders, international agencies like UNDP, WHO authorities and industry associations to make special incentives that may be legally applied, efficiently and effectively in the country and be published to let foreigner investors know them and be attracted to invest in pharmaceutical industries in Rwanda.

## RECOMMENDATIONS

Attracting foreign investment in the pharmaceutical industry in Rwanda requires a comprehensive strategy that addresses various aspects, from regulatory frameworks to infrastructure development. Here are some recommendations to encourage foreign investment in the pharmaceutical sector in Rwanda

Streamline Regulatory Processes, simplify and expedite the regulatory approval processes for pharmaceutical products. A transparent and efficient regulatory framework encourages investment.

Investment Incentives, offer targeted incentives to pharmaceutical companies, such as tax breaks, import duty waivers on raw materials, and support for research and development (R&D) activities.

Infrastructure Development, invest in pharmaceutical manufacturing infrastructure, including industrial parks and facilities that meet international quality and safety standards.

Intellectual Property Protection, strengthen intellectual property rights protection to encourage innovation and protect pharmaceutical investments.

Local Production Support, provide support for local pharmaceutical manufacturing by offering incentives to companies that invest in production facilities within Rwanda.

Research and Development (R&D) Funding, establish funding mechanisms to support R&D efforts in the pharmaceutical sector, including partnerships with research institutions and universities.

Capacity Building, invest in training and capacity building programs to enhance the skills of the local workforce in pharmaceutical manufacturing and research.

Market Access, leverage regional trade agreements and organizations like the East African Community (EAC) and the African Continental Free Trade Area (AfCFTA) to facilitate market access for pharmaceutical products manufactured in Rwanda.

Quality Control and Certification, strengthen quality control mechanisms and facilitate international certification for pharmaceutical products to ensure they meet global standards.

Public-Private Partnerships, foster partnerships between the government, private sector, and international organizations to jointly invest in and support the growth of the pharmaceutical industry.

Investment Promotion, promote the pharmaceutical sector as an attractive investment opportunity through targeted marketing and outreach efforts to potential investors.

Regulatory Harmonization, work towards harmonizing pharmaceutical regulations within the East African region to facilitate cross-border trade and investment.

Special Economic Zones, consider establishing special economic zones or pharmaceutical clusters dedicated to the industry, offering infrastructure, utilities, and tax incentives.

Research and Innovation Centres, create research and innovation centres that focus on pharmaceutical and biotechnology research, attracting foreign companies and experts.

Market Research and Demand Analysis, conduct market research to identify specific pharmaceutical needs and demand trends in Rwanda and neighbouring countries to inform investment decisions.

By implementing a combination of these recommendations, Rwanda can create an environment conducive to attracting foreign investment in the pharmaceutical sector. It's essential to engage with stakeholders, including foreign pharmaceutical companies, industry associations, and regulatory bodies, to develop a tailored strategy that aligns with the country's development goals and the needs of the global pharmaceutical market.

# BIBLIOGRAPHY

## I. Legal Texts

### A) National legal text

1. The Constitution of the Republic of Rwanda of 2003 revised in 2023
2. law n° 006/2021 of 05/02/2021 on investment promotion and facilitation
3. Law nº 06/2015 of 28/03/2015 relating to investment promotion and facilitation
4. Law n° 007/2021 of 05/02/2021 governing companies

### B) International legal instruments

1. American Uniform Commercial Code sales act, 2007 edition.
2. Protocol Amending the International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading, Brussels, 1979 (SDR Protocol).
3. UNCITRAL Model Law on International Commercial Arbitration of 1985 as amended and adopted in 2006.
4. United Nations Convention on Contracts for the International Carriage of Goods Wholly or Partly by Sea, adopted by United Nations, New York, 11th December 2008
5. United Nations Convention on Contracts for the International Sale of Goods, Vienna 11 April 1980, S.Treaty Document Number 98-9 (1984), UN Document Number A/CONF 97/19, 1489 UNTS 3.
6. United Nations Convention on Contracts for the International Sale of Goods, Vienna 11 April 1980, S.Treaty Document Number 98-9 (1984), UN Document Number A/CONF

## I. BOOKS

1. ALLAN E. FARNSWORTH, WILLIAM F.YOUNG, Contract case and materials, University case book series, 4th edition 1988.
2. BRUNO ZELLER, CISG and the Unification of International Trade Law, 270 Madison Ave, New York, NY 10016, 2007.
3. CHARTERED INSTITUTE OF PURCHASING AND SUPPLY, Effective negotiation in Purchase and Supply, The official CPIS Course book, Easton house, Easton on hill, Starmford, Lincolnshire PE9 3NZ, 2011.
4. HONNOLD JOHN, Uniform Law for International Sales under the 1980 United Nations Convention, University of Pennsylvania, United States, Balton Center, 3rd ed. (1999).
5. Murugi, B.M. et al. (2010) Strengthening pharmaceutical innovation in Africa, Council on Health Research for Development (COHRED)/New Partnership for Africa's Development (NEPAD).
6. Reichman, J.H. (2009) 'Compulsory licensing of patented pharmaceutical inventions: evaluating the options', Journal of Law, Medicine & Ethics 37(2): 247–263.
7. Sigonda, M.N. et al. (2017) 'Medicines Regulation in Africa: Current State and Opportunities', Pharmaceutical Medicine 31(2): 383–397.
8. Tanani, M. (2018) 'Strengthening Efforts to Support the Pharmaceutical Sector in Africa', Ideas for Development.

## II. CASE LAWS

1. Gordon J, Welink J, Potthast VS H, Hansson H, Stahl M Pharmacol. 2012;68: 1611-8.
2. Gwaza L, Gordon J, Welink J, Potthast VS H, Leufkens H, Stahl M, García-Arieta A. 2014; 96:580–8. doi:10.1038/clpt.2014.144.
3. Waning B, Diedrichsen VS E, Moon S. A lifeline to treatment: AIDS Soc. 2010; 13(1):1–

## II. REPORTS, JOURNALS AND ARTICLES

1. United Nations Conference on Trade and Development, Investment Promotion Agencies as Policy Advocates, Investment Advisory Serie: Series A, number 2, New York and Geneva 2008
2. United Nations Conference on Trade and Development, Investment Promotion Agencies as Policy Advocates, Investment Advisory Series: Series A, number 2, New York and Geneva 2008
3. WHO (2011) Local Production for Access to Medical Products: Developing a Framework to Improve Public Health, World Health Organization, Geneva, Switzerland.

## III. ELECTRONIC SOURCES

1. African Development Bank Group (2019). “The African statistical yearbook 2019”. Available at: https://www.afdb.org/en/documents/document/theafrican-
2. International Monetary Fund (2020). “IMF Data Mapper: Real GDP growth”. Available at:https://www.imf.org/external/datamapper/NGDP_RPCH@WEO/OEMDC/ADVEC/WEOWORLD/AFQ
3. IQVIA Institute (2019). The global use of medicine in 2019 and outlook for 2023. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023

4. Sturman, C. “The M-Tiba app is revolutionising healthcare in Kenya”. Published on Global Healthcare website. Available at: https://www. healthcareglobal.com/technology/m-tiba-app-revolutionising-healthcare-kenya.
5. World Health Organization (2019). Global spending on health: A world in transition 2019. Available at: https://www.who.int/health_financing/documents/ health-expenditure-report-2019.pdf?ua=1