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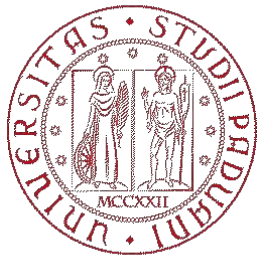

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ACCESS TO MEDICINE AND RIGHT TO HEALTH IN SUB-SAHARAN AFRICA: THE CASES OF KENYA AND SOUTH AFRICA

Candidato:

Amal Bouanane

Relatore:

Prof. Arrigo Opocher

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Ringraziamenti,

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(Abbandonando il tono serio BECAUSE OK TUTTO but I'm no good at being serious, è solo una piccola dedica dopo un piccolissimo traguardo, i wish I can celebrarne TANTI altri insieme)

AND FINALLY A mia madre, di nuovo e fino all'ultimo dei miei respiri.

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Introduction

Overall, there is a significant and rising inequality between so-called high-income nations and middle and low-income countries. This discrepancy is also seen in the field of medicine access: in industrialised nations, medicines are readily available, those considered "life-saving" are subsidised by the government, and the price is in any case proportional to per capita income.

The situation is not always the same in Developing Countries (DCs). The issue of access to medicines is one of the many problems that afflict developing countries, which in some areas of the globe are in situations of extreme underdevelopment, aggravated by food shortages, lack of drinking water, and natural disasters and wars. This is the case of Sub-Saharan Africa, where the situation is the most critical and difficult as will be analysed in the following chapters.

An individual's health condition is affected by these situations, and it is necessary to act on them to prevent the organism becoming weaker and more susceptible to diseases. In addition, a further vicious circle is established: if a disease is contracted, the hospitalisation prevents the person from working, and without income, they are no longer able to purchase food, and the circle continues. Moreover, populations in certain areas are exposed to tropical diseases, which, regardless of other factors, are already very dangerous.

If a disease is eventually contracted, the effectiveness of treatment is often undermined by inadequate infrastructure, the absence of doctors who administer treatment correctly and prescribe the correct medication. In addition, in many communities, healthcare is not even requested because it is replaced by traditional methods of treatment. It is therefore to be emphasised that the problem of access to medicines is part of a more complex problem concerning the health system; however, it was considered necessary to focus on the availability of medicines because in many cases the administration of medicines is the only solution, due to the fact that without them medical staff are limited in their actions. Finally it must be ensured that at least essential medicines are available everywhere and accessible even to the poorest areas.

Since the late 1990s, when the WHO's efforts were joined by representatives mostly from the NGO world, but also from academic and governmental contexts, the problem of access to medications has been increasingly significant on international agendas. The event that brought this issue to the top of the agenda of many interest groups was the negotiation and approval of the TRIPS Agreement for the Protection of Intellectual Property; this agreement mobilised the action of certain NGOs, including MSF (Médecins Sans Frontières), which brought the issue to the attention of world public opinion. Although MSF's criticism is mainly directed at patent-protected drugs and diseases neglected by pharmaceutical research, my interest turned to the fact that many off-patent drugs are still inaccessible; this gave rise to the idea of writing a thesis on access to medicines in sub-Saharan countries and the role of the pharmaceutical industry in providing these goods.

The purpose of this study is to explore the barriers to access to medications in sub-Saharan nations, with an emphasis on the economic elements of the issue. Analysing the superficial obstacles would have been easier, but my aim was to go deeper. Therefore the goal is to thoroughly examine the fundamental obstacles, which are rarely addressed in current events.

The research is introduced by a chapter, the first one, on the situation in undeveloped countries with particular pathological features regarding the right to health. This chapter also provides a current overview of access to medicines, using estimates provided by the WHO.

The second chapter discusses international agreements in the field of intellectual property rights, with a special emphasis on patent rights, which are granted to the innovator to protect the product against imitation. Extensive space is given to the development of the negotiations, the analysis of the text of the TRIPS Agreement, the main international intellectual property protection instrument, and the Doha Declaration on the TRIPS Agreement and Public Health.

Chapter three describes the functioning of the pharmaceutical market in low-income countries, with a focus on sub-Saharan countries. This chapter also includes an analysis

of drug prices. It is specifically examined the debate on the role of prices in access to medicines, and how in recent years there has been a proliferation of consumer price surveys; initially promoted by non-governmental associations independently, later the WHO also took an interest in the issue, and currently a database maintained by HAI (Health Action International) is being released. Given the relevance of price analysis for the purposes of this thesis, it was decided to consider both the surveys conducted by HAI and MSF (Médecins Sans Frontières), as these information are complementary.

The fourth chapter examines the two case studies chosen in the research: Kenya and South Africa. Therefore, it shows how the characteristics of local drug production are determined by the characteristics of Kenya's economic and industrial systems, which are a result of the country's economic history. It also goes into further detail on how Kenya's pharmaceutical industry has grown on this foundation, as well as the prospects presented by more liberalised and competitive marketplaces. Moreover, it discusses some of the governmental decisions that contributed to the growth of the industry, as well as some of the challenges that corporations and governments face.
Regarding the South African experience with pharmaceutical price controls, it was thus deemed to be a good case study to inspire the initiatives of other African governments. Hence it is also described the South Africa's experience with the single exit price (SEP) legislation, which were designed to address these anomalies and to replace mark-up-based retail pricing schemes with fixed professional fees, thereby lowering patient costs.

I. THE RIGHT TO HEALT

1.1 Access To Medicines: Right To Health

The Conference strongly reaffirms that health, which is a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector. [1]

Access to adequate health services and protection from disease risks are a key aspect of both social development and poverty reduction. Many people in emerging countries do not have proper access to important health services. Vaccines, medicines or other medical aid are often not available locally or are unaffordable for those affected. Furthermore, for some diseases there are still no effective drugs or vaccines. This affects above all the populations of low-income countries, such as sub-Saharan Africa.

The issue of global co-responsibility to ensure the fundamental elements of the right to health for undeveloped countries has received increasing attention. Important steps have been taken over the last decade to safeguard this responsibility.

The right to health as a universal human right was defined for the first time in 1946 by the World health assembly (WHO). The text, which was then incorporated into the introduction to the WHO constitution, reads as follows: "The right to the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political opinion, economic or social position»[2].

Back in 2000, the United Nations (UN) formulated eight Millennium Development Goals (MDGs) with the overarching goal of significantly reducing world poverty by 2015. One of the key cornerstones is the achievement of health for all. Under the title 'Changing Our

[1] Declaration of Alma-Ata - WHO | World Health Organisation

[2] World Health Organisation Constitution. http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.(05/06/2021)

World', in September 2015 the United Nations adopted a total of 17 new Sustainable Development Goals [3] by 2030, replacing the MDGs.

The goal No. 3 'Ensure healthy lives and promote well-being for all and at all ages' requires, among other things, to:

- End the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-related diseases and other infections,
- Reduce maternal mortality below 70 deaths per 100,000 live births;
- Prevent all preventable deaths of infants and children under five years of age.

Subsequently, in June 2015, the intergovernmental organisation of the world's major economic powers, the G7, agreed to strengthen existing activities to combat neglected diseases, with a focus on research[4] .

The World Health Assembly, the central body of the World Health Organisation (WHO), also addressed health issues for people in poverty-affected territories in May 2015 and passed revolutionary resolutions, including malaria control and the global vaccination programme. Hence the recognition of the inherent dignity and the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world (Universal Declaration of Human Rights, Preamble).

The Universal Declaration of Human Rights proclaims that all human beings are born free and equal in dignity and rights and recognizes the intrinsic dignity and equal rights of all members of the human family. The WHO Constitution makes the enjoyment of the highest attainable standard of health, one of the fundamental rights of every human being. How can we fail to see that these two messages, formulated more than seventy years ago, are more relevant than ever?

Globalisation means a general acceleration of the flow of goods, services, people and ideas. Yet, in terms of life expectancy, wealth or access medications, the gaps are increasing, both within and between countries. Those who are left behind, who face poverty and disease, victims of a process of marginalisation and exclusion, feel powerless.

In the sphere of human rights, two principles must guide all health-related initiatives: equality and non-discrimination. In this regard, it is important to go beyond statistics and

[3] Further information at https://sustainabledevement.un.org in “Sustainable Development Goals".
[4] Further information on G7 action at https://www.g7germany.de/g7-en, in “Temi G7/G8/G20".

take measures to identify vulnerable and marginalised groups, in order to actively involve them in programmes and make them fully actors in change. In this sense, the aim is not only to ensure that health policies and programmes are inclusive, but also to empower those who are currently excluded.

Therefore, all members of the international community have a legal and moral obligation to help Member States progressively realise the full realisation of the right to health.

This deliberate effort to give human rights a more prominent place in development cooperation was recently confirmed by the adoption of the OECD Development Assistance Committee's first policy document on Human Rights and Development in February 2007. The document reflects the fact that bilateral and multilateral donors are promoting and protecting human rights with positive effects in development cooperation. However, poverty and disease often go hand in hand: people who do not have access to education, adequate nutrition or safe water tend to suffer from poor health. A human rights-based approach to health, with its emphasis on key factors - inclusion, availability, accessibility, acceptability, affordability - can only reinforce the impact of poverty reduction strategies in sub-Saharan countries.

1.1.1 How is health protected in the context of human rights?

The most authoritative definition of the right of every individual to the enjoyment of the highest attainable level of physical and mental health - generally referred to as the "right to health" - is contained in Article 12 of the International Covenant on Civil and Political Rights of 1966.

In order to implement and clarify Article 12, the United Nations Committee on Economic, Social and Cultural Rights adopted the General Commentary No.14 which recognises the importance of health determinants in upholding the right to health. Hence this affirms that the enjoyment of the right to health is closely linked to that of many other human rights which also contribute to the promotion of the rights to food, an adequate standard of living, privacy and information.

In terms of the health discourse General Comment 14 also states that the right to health includes both freedom and rights. The latter also includes the right not to be subjected to medical treatment without consent, torture or cruel, inhuman or degrading treatment or

punishment, and the right to freely dispose of one's own body, including sexual and reproductive matters. In terms of the health discourse, within this general comment there is also the right to access to facilities, goods and health services, the right to prevention and treatment of diseases, the right to a healthy natural and working environment and the right to education. Another important aspect is the participation of the population in health decisions at a national and community level.

Non-discrimination and equality are fundamental components of the right to health. In this regard, States are obliged to prohibit discrimination and to guarantee universal access to health care and health determinants. Hence they should recognise the specific needs of certain categories of the population, such as women, children and people with disabilities (groups that tend to have particular health profiles, including higher mortality rates or increased vulnerability to certain diseases) and take appropriate measures to take into account this specificity.

General Comment 14 establishes four criteria for evaluating the circumstances for achieving the right to health:

- Availability: there must be an adequate supply of health facilities, goods, services and programmes in the field of public health and health care.
- Accessibility: Health facilities, institutions, goods and services must be accessible, without discrimination, to all persons within the jurisdiction of the State Party. The concept of accessibility has four interconnected dimensions:
    1. Non-discrimination
    2. Physical accessibility
    3. Affordability (costs must not exceed the means available);
    4. Access to information
- Acceptability. All health-care facilities, commodities, and services must conform to medical ethics and cultural differences, take into account the specific needs of men and women at different life stages, respect confidentiality, and aim to promote health.
- Health facilities, institutions, commodities, and services must be scientifically and medically suitable, as well as of high quality.

1.1.2 Identification of right holders and bearers of duties

After considering how health is protected in the framework of human rights, in this section it is identified a concrete argument for this right's accomplishment

To address the issues raised by the HRBA (Human Rights-Based Approach) framework and the determinants of health, it is necessary to first identify the various stakeholders, who are divided into two broad categories: the carriers of duties (those responsible for ensuring the effective enjoyment of the right to health) and the holders of rights (those who can legitimately claim their right to health).

Priority should be provided in the framework of PRSs (Poverty reduction strategies) to rights-holders who are likely less able to enjoy the right to health; in other words all individuals and population groups whose access to health care and health determinants is significantly affected by inequality and discriminatory behaviour.

Individuals and organisations that are duty bearers are subject to a variety of obligations and responsibilities related to the right to health and health determinants. Human rights standards help in the identification of duty bearers as well as the nature of their obligations and responsibilities for each right. According to human rights legislation, the state has a critical role in guaranteeing the protection of human rights for all individuals living under its authority.

However, individuals, families, communities, non-governmental organisations, private sector organisations, and the international community all have responsibilities in this regard, although they are less explicitly defined by law. The government is required to regulate the activities of civil society and private sector organisations and to assist them in fulfilling their responsibilities. Therefore, it is beneficial to review national legislation and procedures in order to accurately establish the rights and duties of the two types of actors.

To identify all carriers of relevant duties, it may be useful to map out different services, including maternal-child health services, sexual and reproductive health services. In each of these areas, the various groups and organisations involved at different levels of the community life must be identified, from local and regional authorities to voluntary organisations, international organisations and national government agencies. At the local

level, there are different types of healthcare professionals, including public and private health facilities, traditional healers, birth attendants and pharmacies.

The operators operating at national and international level are also different: parastatals, local NGOs, international NGOs, private organisations, ministries and multilateral development agencies. Identifying the various organisations responsible for ensuring the implementation of the right to health and the determinants of health is an important step in developing the comprehensive and coherent approach that governments need to fulfil their obligation to respect, protect and meet the right to health.

1.1.3 Protection Of the Right To Health

The identification of the holders of rights and the bearers of duties makes it possible to identify the various non-state actors whose actions may have an impact on health.

These actors can be :

- Multinationals, in particular pharmaceutical companies;
- National private companies
- Insurance companies;
- Private health care providers;
- Medical research institutes;
- National and international NGOs.

Many of these organisations can play a positive role in the field of health, but it is the responsibility of governments to control and regulate their activities:

- regulating the marketing or distribution of substances harmful to health such as tobacco, alcohol or certain types of food.
- adopt regulations and measures to ensure their effective application, so that the treatment and disposal of industrial and domestic waste, including agrochemicals, does not harm the health of the workers or local communities concerned.

Governments should also ensure that neither their activities and policies nor the operations abroad of any non-state actor, such as Companies based in their own country can somehow affect the right to health of people living in other countries. This applies in particular to decisions on sanctions or embargoes against a country, the negotiation of

trade or customs agreements and the regulation of the global activities of national pharmaceutical companies.

1.1.4 Assessing institutional Framework and capacity gaps

The identification of rights holders and carriers of duties should reveal a complex network of organisations whose actions can have an impact on the health of the poor and marginalised. It is precisely in the relationship between right-holders and the bearers of duties that difficulties in access to health care and health determinants are rooted. Resources and services are likely to reach the poor more easily and respond better to their needs when right holders can participate, directly or indirectly, in the decision-making process.

The examination of healthcare institutional and policy frameworks is a critical component in the growth of the health sector. Furthermore, examining institutional frameworks and capacity issues that significantly impact the interaction between rights holders and duty bearers might provide some reference points for government measures targeted at increasing impoverished people's access to health care. The word "institutional framework" refers to the rules and processes that define rights, obligations, responsibilities, individual decision-making involvement, and financial resources. The term "capacity" refers to the collection of skills, knowledge, and information that individuals require in order to assert, exercise, and participate in decision-making (OECD-Chapter 8. Institutional framework)[5].

An examination of institutional frameworks and capacities is likely to reveal that the poor have almost no way to influence the behaviour of organisations whose activities have a significant influence on their health and life. The major financial and capability issues that are impeding government efforts to enhance the health of the excluded.

In many countries, a human rights-based examination would most likely reveal that administrative accountability and local government procedures serve the interests of elites and that service monitoring is ineffective. In these situations, there are mechanisms

[5]https://www.oecd-ilibrary.org/docserver/9789264305328-12-en.pdf?expires=1662357429&id=id&accname=guest&checksum=FB5A8BFE99BD664491A99A3910FC6795

that can be used to create a more effective accountability system between service providers and excluded and marginalised groups. This might involve using a reporting system or doing community monitoring.

In addition, Instruments that can substantially assist the establishment of indicators, monitoring, and reporting of implementation are available in countries where national legislation provides a minimum level of rights in the field of the right to health or where a charter of patients' rights has been adopted. Access to information is critical to the effectiveness of community monitoring since it allows individuals to compare the performance of local health services to that of other organisations.

Greater participation in the management of local health services can help improve the efficacy of authorities responsible for the administrative component of the accountability process, such as local and regional health authorities. The systematic development of local responsibility mechanisms can also contribute to improvements in service quality, service utilisation, and health conditions.

1.2 Access to Medication: An Anthropological case

The importation of medication, which is meant to be universal and satisfy North-defined norms, into South nations becomes a topic of research for the social sciences, particularly anthropology.

Anthropologists were the first to treat medications as a social object. The work of Sjaak Van der Geest and Susan Reynolds Whyte is crucial in highlighting the social role of the medicines by asking: Why are medicines so attractive in so many different cultures? What social and symbolic processes do they facilitate?" (Van der Geest, Whyte 1989: 345). The authors emphasise the drug's spread as a factor that extends beyond the bounds of its original place: <<"Medicines" are substances used in treating illness. In this article we want to suggest that the "charm" of medicines, both in the Western world and developing countries, arises from their concreteness as substances. Medicines are things>> (Van der Geest, White 1989: 345).

Medication is presented as a signifier, which means that they are moveable objects with a variety of social meanings beyond their primary purpose: "we consider medications as

commodities, the value of which is agreed upon and transactable, but the precise meaning of which is varied." And the authors add: "as concrete items, drugs are useful to ponder with"[6] (Van der Geest, Whyte 1989: 346). The value of medications beyond the economic value defined by the price: it is influenced by the social environment and the regulatory system in which the medication is adopted.

The medication is included as a "social object par excellence that is part of everyone's regular existence, regardless of society; the medicine has a social life' that involves a diverse range of actors with different actions: policies, suppliers, distributors, prescribers, Sellers, and Users" (The Charm of Medicines:1). Hence it is necessary to consider the anthropological approaches to medicine, as well as all the representations and strategies of actors crystallised around them. Therefore, we must not reduce it only to its value of use determined by its biopharmaceutical efficacy: “Despite the importance attributed to the definition of a drug in pharmaceutical regulations, this concept covers a very diverse reality” (Daburon Garcia 1999). Medicines therefore should be considered as a “travelling, transversal object, which involves a multitude of approaches from a set of heterogeneous sites in health, economy, technology, etc.

The industrial Pharmacy carries within it a major paradox: on the one hand, it is the very product of the capitalist market and on the other hand, its diffusion in society has generated the rise of its detractors: the promoters of public health. The process of drug industrialization underlies the construction of capitalist social relations between the various stakeholders interested in the drug (companies but also public health actors, activists, etc. who formulate demands arising from this capitalist order). The history of the industrialization of the medicines, therefore, is both its transformation into a standardised commodity and the institutionalisation of conflicting social relationships based on the consumer payment model for innovation (via the patent model).

[6] 11 This insistence on the materiality of the drug is reminiscent of the sociology work of Bruno Latour and Steve Woolgar on laboratory life (Latour 1979).

1.3 The "Big Three" - Malaria, HIV/AIDS, Tuberculosis

1.3.1 Overview of neglected diseases in Africa

With the goal of examining what the barriers to drug access are in Sub-Saharan nations, it is also vital to examine which diseases impact the health condition significantly. In this regard, the three most common and deadly diseases in Sub-Saharan Africa will be discussed in this section.

The tropical climate of Africa makes the continent the largest reservoir of infectious diseases, in particular malaria, tuberculosis (TB) and acquired immunodeficiency syndrome (AIDS), as well as frequent epidemics of polio, meningitis, cholera, pandemic influenza, yellow fever, measles, hepatitis, and tetanus[7]. With the increasing adoption of Western lifestyles in Africa, there has been a paradigm shift and the incidence of non-communicable diseases (NCDs) has also increased, undercutting the demand for drugs for chronic diseases[8].

According to World Health Organisation forecasts, the contribution of non-communicable diseases to health care in Africa will increase by 21% until 2030. Meanwhile, the population will continue to suffer from infectious and parasitic diseases. The limited economic accessibility of governments and the general population to healthcare and pharmaceuticals and the high dependence on external funding will be the main restrictions of the market.

Malaria, HIV/AIDS, and TB are by far the most important poverty-related illnesses in terms of victims and disease burden. These three illnesses kill around three million people worldwide each year, primarily in underdeveloped nations. Tuberculosis and HIV co-infections are a particular problem: people with HIV contract tuberculosis particularly frequently and severely, and interactions between their drug treatments are sometimes problematic (World Health Organisation WHO).

[7] https://www.statista.com/statistics/1029337/top-causes-of-death-africa/

[8] K.E. Jones, N.G. Patel, M.A. Levy, A. Storeygard, D. Balk, J.L. Gittleman, et al. Global trends in emerging infectious diseases Nature, 451 (2008), pp. 990-993

The suffering caused by poverty-related diseases is immense. Simple statistics on deaths do not adequately reflect this. However, according to the WHO, in 2017 more than three million people in the world died from neglected and poverty-related infectious diseases. More than 90% died because of the "big three" (malaria, HIV/AIDS and tuberculosis). Although the 17 NTD group causes significantly fewer deaths (about 5%), it is an urgent global health problem when considering other factors (such as disability).
In addition to mortality, it also includes the possible reduction of life expectancy and loss of quality of life due to other health conditions (for example, disability, chronic illness, inability to work). One measure of the burden of the disease is the so-called DALY (Disability Adjusted Life Years lost).

1.3.2 AIDS: the 21st Century emergency

In July 1982, an acronym appeared in the international scientific spotlight with which we have now learned to live: AIDS, an acronym (in English) of Acquired Immuno-Deficiency Syndrome. Since then, the "end-of-millennium disease" has claimed millions of victims worldwide, and at the current state of research the best drugs available still have limited effectiveness in combating it.

The worldwide community has responded strongly to the AIDS crisis, with programmes aimed at finding a "global solution to a global issue". These initiatives have followed two major directions: the sex education and prevention strand, as methods to minimize the risks of HIV infection, and the strand committed to enhancing and enabling access to so-called "important" medications for all AIDS patients across the world, without regard for race or ethnicity. Because HIV/AIDS is a relatively new phenomenon, most essential drugs are protected by patent, and patents are subject to rigorous international regulatory requirements. Here is the origin of the encounter-clash between world health, and intellectual property, which is one of the points analysed in this research (Chapter 2).

Discovered in the United States in 1983, the human immunodeficiency virus (HIV) is now one of the world's leading killers. More than 23 million deaths worldwide are directly attributable to HIV, including 19 million in sub-Saharan Africa alone, where

more than two thirds of the 33 million people affected by the virus live (UNAIDS, 2008). In addition to this already alarming picture, the effects of the disease do not stop at the medical level.

Besides from the health sector, what distinguishes HIV/AIDS is its influence on development. In fact, the illness strikes individuals during their most sexually active years, which also happen to be their most productive. The disease undermines three pillars of development: economic growth, human capital and the investment climate. Macroeconomic calculations have made it possible to assess the consequences of AIDS on the economy of developing countries: they are lost from one to two points of GDP growth (gross domestic product) when 10% of the population is infected (Couderc and Ventelou, 2005). This is a huge problem especially for a continent where half of the population lives below the poverty line and which needs to achieve an economic growth rate of 5% a year just to maintain the status quo. HIV/AIDS enhances poverty and contributes to the growing inequality between the developed and developing world. Because the impact of HIV/AIDS on development is undeniable, it must be treated as a separate development issue.

A variety of socioeconomic, societal, and epidemiological variables influence the HIV/AIDS epidemic. These factors are diverse and complicated, they interact with each other, and they have a dual causal relationship with the HIV/AIDS epidemic. This is one of the reasons why the epidemic has progressed worse than even the most pessimistic projections. In fact, the pandemic is spreading due to favourable economic, sociocultural, and epidemiological conditions. As a result, as previously explained, it aggravates these circumstances, notably through its influence on the labour, institutions, and even illnesses.

As a result, the HIV/AIDS epidemic in underdeveloped nations has become a vicious spiral. Although extensive research has been conducted on the economics of HIV/AIDS over the last decade, most of it has focused on impact studies and evaluations of the epidemic's effects on various elements of economic life

1.3.2.1 Socio-economic determinants

The spread of HIV/AIDS has now reached epidemic levels. Although the mechanisms that determine viral transmission from one person to another are simply individual, the disease's pandemic nature is related to far more complicated and global factors, whose influence on the HIV/AIDS epidemic has previously been examined by certain writers (Over, 1992, Bonnel, 2000, Stillwaggon 2000 and 2006, Nattrass 2006).

Economic variables impact the prevalence rate of HIV/AIDS indirectly by establishing an environment that increases risk scenarios and does not always allow individuals to use available information. These include national income, poverty, income inequality, gender discrimination, education level, degree of urbanisation, mobile population proportion of total population, access to information, healthcare, and governance.

Level of education: The level of education is a decisive factor in the progress of the pandemic. Initially, the disease impacted individuals with variable levels of education throughout the continent, but as the pandemic spreads, the more educated parts of the population become less and less affected. The highly educated people, for example, are the most aware about prevention.

Access to information: Most infections occur because people are unaware of the existence of the disease and, even if they are, they do not have adequate information about the way of transmission (UNAIDS, UNICEF, 2002). Information and education have a synergistic effect because information campaigns are often carried out through posters, radio and television announcements, generally in the official language, which may differ from local languages.

Access to health services: Failure to treat sexually transmitted illnesses is the primary channel through which access to health care impacts the HIV/AIDS epidemic Sexually transmitted infections (STIs). According to Lurie (1995), structural adjustment programs are responsible for the decline of health systems in Africa because they created the conditions for the spread of the epidemic through budget cuts that affected health systems just when the country was vulnerable and should have been better equipped to deal with other infectious diseases, including STI. Therefore, these policies imposed on African

countries have led to a decline in access to preventive health care and care, such as HIV/AIDS prevention programs.

Governance: the influence of governance on the evolution of the HIV/AIDS epidemic essentially passes through the priority that the government gives to HIV/AIDS as a real public health and even development problem. Many African countries' disastrous economic state is due to weak governance rather than adverse international conditions. In a corrupt political environment, policymakers may not have the incentive to invest sufficiently in HIV/AIDS prevention activities. As a result, good governance is considered a factor in slowing down the epidemic.

1.3.3 TUBERCULOSIS

In 1993, the WHO defined tuberculosis (TB) as a global public health emergency, in response to the constantly increasing incidence and the spread of multidrug resistance. Currently 95% of cases and 98% of deaths attributable to TB occur in developing countries[9]; Uganda has been included by the WHO among the 22 countries that together contribute to the 80% of cases of TB in the world.

The "Global tuberculosis report 2020" confirms that tuberculosis is among the top ten causes of death in the world. It is estimated that in 2019 10 million people received a new diagnosis of TB (accident cases), 88% of whom were adults (age> 15 years), and 8.2% people infected with HIV. Although the global incidence of tuberculosis is decreasing, based on current data (available until 2019), it will not be possible to reach the goal of reducing it by 20% between 2015 and 2020 (in the period 2015-19 the reduction was 9%). Furthermore, it represents, according to World Health Organization (WHO), one of the most leading causes of death worldwide.

The unprecedented growth of the tuberculosis epidemic in Africa is attributable to several factors, the most important being the HIV epidemic. Although HIV is Africa's leading cause of death, tuberculosis is the most common coexisting condition in people who die from AIDS. Autopsy studies show that 30 to 40% of HIV-infected adults die from

[9] https://www.who.int/health-topics/tuberculosis

tuberculosis[10]. Among HIV-infected children, tuberculosis accounts for up to one in five of all deaths.[11]

The association between HIV infection and tuberculosis stems from two distinct processes. In some cases, populations with latent tuberculosis acquire HIV infection, which increases 100-fold the risk of reactivation of tuberculosis. In other cases, people with HIV-induced immunosuppression acquire new tuberculosis infections and are at extraordinarily high risk for active tuberculosis. This cycle of infection and disease is amplified by the interaction between patients with active tuberculosis and those with HIV infection in clinics, hospitals, and the broader community.

The ability of African health care systems to respond to, manage, and contain the growing number of cases of tuberculosis is constrained by limitations of funding, facilities, personnel, drug supplies, and laboratory capacity. Although many Emergency Plans has been taken for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis, and Malaria have donated large amount of money to help address Africa's health problems, most of the money has been earmarked for HIV, with a lesser focus on tuberculosis.

1.3.4 MALARIA

Malaria in the sub-Saharan Africa remains a problem whose severity and urgency exceed local resources. It poses itself as a challenge to international solidarity, especially in the field of protection of local populations. Perspectives in this area are quite different depending on the epidemiological characteristics of malaria in particular its stability.

Furthermore, it is estimated, from data provided by the World Health Organisation (WHO), that currently lives in areas with endemic malaria disease about 40% of the world population, that 300-500 million cases of symptomatic malaria occur every year (90% in Africa), that the annual lethality for this disease fluctuates between 1 and 3.5 million

[10] Ansari NA, Kombe AH, Kenyon TA, et al. Pathology and causes of death in a group of 128 predominantly HIV-positive patients in Botswana 1997-1998. Int J Tuberc Lung Dis 2002;6:55-63

[11] Chintu C, Mudenda V, Lucas S, et al. Lung diseases at necropsy in African children dying from respiratory illnesses: a descriptive necropsy study. Lancet 2002;360:985-990

patients (in Africa, 1 million children/year under 5 years of age); it is estimated that 300 to 500 million clinical cases attributable to malaria occur each year, and at least one million deaths, most of them children[12].

The exact number of deaths is inaccurate as most deaths occur at home and it is often difficult to spot symptoms. However, more than 40% of the world's population is at risk of malaria. Frequently, groups of migrants or refugees migrate from one area to another, risking contracting a disease for which they are unprepared.

[12] https://www.who.int/news-room/fact-sheets/detail/malaria

2 INTERNATIONAL AGREEMENTS AND PATENT RIGHTS IN ACCESS TO MEDICINES

The patent is the most legal instrument through which those who have created an invention are granted a temporary monopoly of exploitation of the invention, consisting of the right to exclude third parties from implementing it and profiting from it in the territory of the granting State, within the limits and conditions set by law[13].
In this Regard this Chapter deals with international agreements in the field of intellectual property rights, as well as the evolution of the negotiations, to the analysis of the text of the TRIPS Agreement, the main international instrument for the protection of intellectual property, and the Doha Declaration on the TRIPS Agreement and public health.

2.1 A Brief History Of Patent Rights

The first patent recognized in history, was granted to the Venetian Filippo Brunelleschi in 1421 for an innovation concerning the transport of marble[14].
The first attempt to form a multilateral agreement for the protection of industrial property occurred in 1883, when the Paris Convention was signed for the Protection of Industrial Property. The Paris Convention gained popularity year after year because, while it allowed for common discipline, it was also flexible enough to allow states to pursue the best policies they desired.
In recent decades, attempts have been made to standardise intellectual property legislation at global level, supported exclusively by the most industrialised countries; the only instrument available until the 1990s was the WIPO (World Intellectual Property Organisation)[15].

[13] https://www.wipo.int/patents/en/
[14] Ideal Matter: Globalisation and the Intellectual Property Debate, Centre for a New Europe
[15] WIPO is one of the specialised agencies of the United Nations (UN) Organisation for the Protection of Intellectual Property. It currently has 181 members and administers 21 international treaties; its seat is in Geneva, Switzerland. It was formally established by the Convention for the Foundation of the World Intellectual Property Organisation signed in Stockholm in 1967; it became a specialised agency of the UN in 1974.

2.2 Uruguay Gatt Round

In 1947, following World War II, the General Agreement on Tariffs and Trade (GATT) system was created, to supervise the operation of the international market, giving special attention to potential tariffs and charges that constituted trade obstacles. This agreement was first signed by 23 nations, but since then, more and more countries have negotiated agreements, allowing them to immediately join the GATT.

For the first time, agreements were reached on services and intellectual property, as well as on the traditional trade in goods. Hence the issues were delicate and difficult to stipulate between Member States. For this reason, the negotiations lasted so long and ended only in 1994 in Marrakech.

Among the significant developments brought about by this agreement was the establishment of the WTO (World Trade Organisation) as an entity, with executive bodies and hence increased power.

The negotiation and approval of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, which deals with the commercial aspects of intellectual property rights (IPRs), was relevant to patent rights. This agreement included, for the first time and unexpectedly, the protection of intellectual property in the multilateral trading system.

Previous agreements and treaties had partly standardised intellectual property legislation mostly in countries that already had trade relations. These laws, however, were not considered adequate to regulate an increasingly "globalised" international market, as they did not deal at all with certain topics and were incomplete on others.

2.3 The Trips Agreement: A Critical Analysis

For many observers, the negotiations during the Uruguay Round for the definition of the TRIPS Agreement were conducted by interests, especially those of the most innovative technology multinationals. As a result, it is considered that the entire text of the Agreement is explicitly in favour of the holders of patent rights. The assertion of the

interests of multinational industries also on individual governments, responds to a strategy that in recent decades has led to a change in economic thinking and new political choices. Since the 1980s, in fact, we have witnessed the emergence of the current of liberal thought, especially in the most influential circles of politics and economics. This ideology advocates the minimum intervention of the State, the reduction of taxes on companies so that they can invest their profits to the fullest and their advantageous position on the market can only raise the standard of living of citizens. This is the ideal model in a perfectly competitive economy.

Moreover, by refuting this ideology, the economic theory has begun to discover situations of imperfect competition and it has been inferred that a system of perfect competition is difficult to achieve, especially in some sectors, because there are increasing economies of scale and as regards demand there are several variables that affect consumer behaviour, including advertising. At this point the companies began to study marketing policies to exploit the balance of imperfect competition, sometimes creating oligopolies and monopolies. What matters now, in short, is no longer the production of the maximum quantity at the price of competition, but the reduction or differentiation of the offer to capture the largest possible part of what is called the consumer's income.

In modern economies transitioning to a service society, technical dominance is critical. The international division of labour leads to the relocation of manufacturing activities in the South of the world, while the management centres are concentrated in the Northwest. Every government then has as its aim the maximisation of the interest of its nation. As a result, it tends to safeguard the invention that results from investments made in its territory by granting a patent right.

If companies could protect their intellectual property rights within the borders of the industrialised world, if not exclusively at national level, the same could not be said for Sub-Saharan countries. It should be noted that, before the ratification of the Agreement, the protection rules were substantially different in the USA and the (The European Economic Community) EEC. In the United States, the protection of inventors' rights was paramount and only in a few cases it was possible to intervene when monopolies existed. In the EEC the priority has always been the diffusion of technology, so the patent was a

way to recognize the ownership of the right and the merit, but there were widespread practices of assignment of patents against the payment of a fee (royalties).
As for the Sub-Saharan countries, however, there was no system of intellectual property protection for most of them. Moreover, when the process of transferring technology from the north to the south began, many Sub-Saharan countries exploited inventions discovered by American, European, or Japanese multinationals.

2.3.1 Effects Of The Trips Agreement: From The Uruguay Round To The Doha Declaration

As provided for in the 1994 GATT text, the WTO meets at least every two years to conduct new negotiations and tackle problems which have not yet been resolved. These were held in Singapore in 1996, Genoa in 1998, Seattle in 1999 and Doha in 2001. Negotiations in Genoa and Seattle were accompanied by protests from activists claiming global justice. They claim that since the establishment of the WTO, its decisions have in most cases been unfavourable to the developing countries, particularly the African ones, thus increasing the already large wealth gap between them and the more industrialised nations. This movement, which gathers the support of many NGOs aimed at volunteering and cooperation worldwide, calls for greater participation of African countries in the negotiations. According to them, they are led almost exclusively by the US and the EU and require that the NGOs themselves be involved.
The violence in Genoa and the widespread demonstrations which accompanied the ministerial meeting in Seattle have forced the influential members of the WTO to consider some of their demands, especially because the attention drawn to public opinion by these protest campaigns has partly undermined the credibility of the WTO. In fact, it is vital for a supranational organisation to be impartial, instead of being led by special interests.

One of the reasons that led the Protestants to organise demonstrations and campaigns against the WTO concerns the scope of TRIPS. It is specifically mentioned that the TRIPS Agreement restrictions have greatly hampered access to crucial medications in Least Developed countries (LDCs), including African nations. Although the WTO knew some

issues on the regulation of patent rights, they remained outstanding. Moreover, the WTO never discussed the subject during the Rounds in Singapore and Genoa.

The pharmaceutical multinationals have first pressed for the introduction into the text of the Agreement of the special rule in favour of chemical-pharmaceutical patents, which provides that all members of the Agreement must register the chemical-pharmaceutical patents. This is the so-called "mailbox" practice and was granted because the confederations of these multinationals have long complained about the lack of protection of their patents; they cost years of research and investment, after which the combination of the components can be easily copied. The rule in question, not only requires all Members, even the least economically developed, to grant the patent right to chemicals-pharmaceuticals, but also obliges patent holders to allow the exclusive right to market on the territory of that state (exclusive marketing right) for five years after the start of marketing.

The years 1996 to 2001 have been critical for African countries, because they had to face many difficulties created by the new system and they have obtained little help from the industrialised countries, indeed they have often been disadvantaged much more than necessary.

The first action by the industrialised countries to weaken or even neutralise the rules in favour of the African countries contained in the Agreement, was to put pressure on the Members to implement legislation in favour of owners rather than the public interest, often in the form of consultations, even on request, as was the case for Uganda. This country has asked the US to send experts to be able to approach national ministers to draft legislation in compliance with the TRIPS Agreement.

The Ugandan Government's decision to reform intellectual property legislation dates to the early 1990s and the draft law prepared by US experts was ready in 1998, ahead of Uganda's rightful deadline, as a developing country. The legislation suggested in this draft law has been much stricter than that provided for in the TRIPS Agreement.

Other countries have been blackmailed by the US Government, which, through the "Section 301 investigation[16]" of the Omnibus Trade and Competition Act Section, refuses to conclude agreements with countries that do not guarantee the minimum

[16] https://ustr.gov/issue-areas/enforcement/section-301-investigations

indicated by them in the protection of TRIPS. American standards go far beyond those of the Agreement and as has been demonstrated on multiple times, the pharmaceutical cartel holds significant power over the US government. South Korea, Argentina, Brazil, and certain Central and North African nations were among those affected by "section 301."

The fear of being discriminated against by the world's most important economy with the consequence of losing further positions in the global ranking or of making mistakes and risking being sanctioned has led many countries to adapt to the demands of the most industrialised countries.

The purpose of the TRIPS Agreement is to standardise legislation in the field of intellectual property rights. However, the negotiators did not consider the fact that, given the importance and necessity of the recognition of the right of invention, each country has different needs in the field of technology and innovation. While a strong intellectual property discipline benefits developed nations since they are the driving force behind research and innovation, the same is not true for underdeveloped countries. They prefer a more competitive market and lower prices since they do not receive any advantage from the protection of patent holders, not being innovators, but rather imitators. Moreover, Europe and the United States themselves have been able to become an economic power thanks to the transfer of technology, often free of charge. Each country has different needs, but this has not been considered, at least in practice.

Moreover, each production sector also has its own needs: while some countries have adapted to the use of obsolete technologies in some sectors, in others they have been unable to resist. One example is the pharmaceutical sector; US multinationals are very powerful and try to delay the expiry of a patent as much as possible. The issue of access to medicines has been raised following the uncontested spread of the HIV/AIDS virus.

First, it should be noted that in Sub-Saharan countries the government takes very little action in the field of health. This means that in most cases, the expense of treatment is covered by the patient; the already indebted southern states cannot afford to spend too much on public services. Expenditure on medicines in proportion to total health expenditure is also higher in poor countries. Furthermore, the price of drugs has a

significant influence on total expenditures and impacts the availability of treatment for a larger number of people. This is a very significant difference. In the North, governments act in their interest to regulate prices; in the South, generally, consumers often remain at the mercy of prices set by the market.

Prior to the Agreement, many countries were able to cope with the serious spread of diseases mainly by producing or buying copies of original medicines abroad, drastically reducing prices and ensuring access to essential medicines for a good number of patients. The lack of patent protection had also allowed the spread of chemical industries that, not always having resources for innovative research, were limited to copying the medicines already on the market. The pharmaceutical sector was thus the first to benefit from the entry into force of the international system of protection. This has given the multinationals a monopoly power at a global level.
Before the Agreement, they protested about the damage created by the numerous drug makers. A drug is defined as generic in these cases: when it is produced identical to the original, but in a country where the exclusive right of the holder is not recognized, when the final product is similar, but not identical to the original or when it is produced following the expiry of the patent (WHO-prequalified generics)[17]. However, these products feed a vast market in the South of the world, where most people are not economically able to obtain medicines at the prices charged by multinationals.

The pharmaceutical industry is a sector that requires large investments, but then enjoys large economies of scale: the marginal cost decreases as the quantity produced increases as the incidence of Research and development (R&D) costs decreases. In the absence of competition or regulation it can maintain the monopoly price and achieve high profits. Multinationals claim that profits must be reinvested to fuel research, yet much of the profits are used to finance marketing, advertising, and business management.
Initially, multinationals exploited the characteristics of specific markets; subsequently, they severely decreased prices since they discovered that the laws of emerging nations permitted parallel imports and the creation of generics, deteriorating their market position.

[17] https://apps.who.int/iris/handle/10665/331014?locale-attribute=fr&

2.3.2 South African Case

In 1997, the government of South Africa approved an amendment to the pre-existing legislation on patents and public health, to comply with the requirements of the TRIPS Agreement. The result was the "Medicines and Related Substances Control Amendment Act" which amended the "Medicines and Related Substances Control Act" of 1965. The new legislation provided for the modalities within which the Minister of Health can apply the compulsory licence and admitted international exhaustion. Section 15C of the Statutes states: "the Minister may provide for the conditions under which a drug, if identical in composition, has the same standard quality and is attributed to the same holder of the patent already registered in South Africa, but is imported by a person other than the holder of the certificate of registration, from any place of production of the original holder comes, may be imported".

This rule clearly concerns parallel imports, but does not refer to generic products, which in fact receive limited consideration in this new legislation. The Minister has the power to act to reduce the fragmentation of markets, since, if the original patent holder places the same product on other markets at lower prices, the Minister can allow them to be imported. This rule leads to increased competition, since drugs can be imported from any place of production, so even those produced by licensees. If information can be easily acquired, this practice produces market harmonisation.

To prevent the drugs to be imported from going on illegal rounds, the law also provides that products can only be imported and sold by a person with a permit from a regulatory authority. The law provides for the compulsory licence in line with the requirements of art. 31 of the TRIPS Agreement, when there is a national emergency, extreme urgency, or non-commercial use by the public administration. The other case envisaged is when anticompetitive practices on the part of the holder exist. In this case, the compulsory licence applies when the proprietor or licensee imposes a price significantly higher than the estimated costs for the product because he abuses his dominant position. According to the law's interpretation, the government is not permitted to import medications produced under a compulsory licence, unless the licence is provided to deal with a national emergency. However, if South Africa is facing an urgent public health situation,

it is believed that it has the right to import generic medicines produced by compulsory licensing.

As is the case with the HIV/AIDS epidemic: many countries are facing an emergency, as the virus spreads more every year. It is a fact that several generic producing countries can provide much cheaper drugs than multinationals. Although the law of the "Medicines and Related Substances Control Amendment Act" adheres to the TRIPS Agreement, the American pharmaceutical multinationals believed it was too permissive.

In 1998, about forty pharmaceutical multinationals, led by the Pharma association and supported by the US government, filed lawsuits against the government of South Africa, the South African Pretorial High Court. The accusation was that it had passed patent rights legislation that gave greater importance to public health, and allowed solutions on parallel imports, compulsory licensing, and the production of generics locally.

South Africa is the country with the highest incidence of the HIV virus in the world (WHO) and every year thousands of people die because of the impossibility of access to adequate medicines. With the price applied by multinationals, only 1% of patients can access treatment[18]; instead, thanks to the production or import of generics, the price has fallen considerably.

The multinationals claim that the production of generics is illegal; that the government should first spend on improving health infrastructure, rather than dwelling on reducing drug prices. They further believe that, due to generic competition, they will no longer be able to recover their costs and thus reduce investment in R&D even for diseases that affect the South the most. Moreover, they are also convinced that imitation discourages local research. However, since the beginning of the lawsuit they have significantly reduced prices to encourage the government to buy from them, stating that often generics are no longer valid.

NGOs in support of South Africa claim that the right to health has priority over profits; that Sub-Saharan Africa may benefit from the Agreement's advantages to protect public health and food, including the use of the compulsory licence. The lawsuit carried on until 2001, when the corporations agreed to drop it due to public pressure from all over the

[18] HIV System Navigation: An Emerging Model to Improve HIV Care Access, 2007

world. As a result, the South African government was able to restart production of HIV/AIDS medications.

2.4 The Doha Declaration On The Trips Agreement And Public Health

As a result of increasing pressure and appeals from the major NGOs around the world, in particular Médecins Sans Frontières, Oxfam International and consumer associations, which also attracted public opinion, the WTO had to take the serious and unexpected decision to address the problems related to the TRIPS Agreement, even if limited to the area of public health.

In preparation for the Fourth Ministerial Conference in Doha, Qatar, in November 2001, an internal TRIPS Council debate on "intellectual property and access to pharmaceuticals" was conducted in June 2001. The participating Members have submitted their requests and opinions. In particular, the representatives of the Sub-Saharan countries explained in detail the problems they had to face and the solutions that had to be taken. This happened without detracting from the rules of the Agreement but only by leaving the Members free to implement. The discussion led to the inclusion of this topic in the negotiations held in Doha that produced, as regards intellectual property, the "Doha Declaration on TRIPS Agreement and public health" ("Doha Declaration on the TRIPS Agreement and Public Health", more commonly the "Doha Declaration"). The negotiations were followed by the persistent media presence of the most major international NGOs, which drew a remarkable amount of public interest.

The Doha Declaration consists of seven paragraphs. It opens by saying that the WTO recognises that many developing countries face serious public health shortages, especially in the face of serious dangers such as HIV/AIDS and diseases that are not yet marginalised such as malaria, tuberculosis, and other epidemics.

The declaration concerns the relationship between TRIPS and public health, not between the Agreement and access to medicines to eradicate diseases that have led to an epidemic at a certain period. Initially some members of the WTO wanted to address the declaration

only to those situations of serious epidemics (such as AIDS) or even pandemics; the latter are epidemics that affect vast regions or even the globe.[19]

Continuing the analysis of the text, it is stated that the TRIPS system must move towards the international resolution of the problem of access to adequate health protection. Members agree that the Agreement should not hinder them in taking appropriate measures to protect public health, therefore "states that the Agreement can and must be interpreted and implemented in such a way as to guarantee every member of the WTO the right to protect public health and in particular access to medicines for all" (Doha Declaration on the TRIPS Agreement and Public Health).

The Doha Declaration is the result of a ministerial conference, at which all members had to be present. A ministerial decision has legal consequences for WTO members and entities. Its purpose is to provide a legal interpretation of the TRIPS Agreement: it directs their actions. Finally, it must be understood that the Agreement and the declaration are not conflicting: in the case of measures taken for the protection of health, the former must not be an obstacle to the other.

[19] https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

3 ACCESS TO MEDICINES: THE ROLE OF PRICES

3.1 The demand for pharmaceutical drugs

Individual demand for medications in underdeveloped nations contrasts from inflexible demand in high-income countries, where health is the privilege to engage in any other activity and wealth and health systems give access to almost any treatment.
Because the average age at birth is much lower in poor areas, life expectancy includes the understanding that life may end prematurely. Diseases are the leading cause of mortality, but they are not the only ones; poverty, malnutrition, weakness, and illness are all interconnected, and the underdevelopment condition promotes the spread of pathologies. As a result, health care receives less attention.

3.1.1 Public funding: overall public and private expenditure in emerging countries

Table 1 summarises various health and pharmaceutical expenditure indicators for low, medium-low, and medium-high income nations.

INCOME	HEALTHCARE EXPENSE PER CAPITA (INT.$)	%PRIVATE HEALTHCARE EXPENSE OUT OF TOTAL EXPENSE	% PHARMACEUTICAL EXPENSE OF THE TOTAL HEALTH SPENDING	PHARMACEUTICAL EXPENSE PER CAPITA (INT.$)
LOW	20	47.45	26.5	5
MEDIUM-LOW	95	41.57	24.2	21
MEDIUM-HEIGHT	304	34.18	22.6	65

Source: Data reported by "the World Medicines situation", Appendix 2

Although pharmaceutical expense is included in health expenditure, the latter still represents the number of resources committed to public health. As a function of per capita income, health spending per capita in underdeveloped nations is much lower than in high-income countries. The results in Table 1 illustrate that as wealth rises, so does per capita health expenditure.

Regarding health spending, it is also important to highlight the percentage of health expenditure carried by private individuals; in economically poor nations, health expenditure weighs more heavily on citizens, whereas in wealthy economies, the welfare state plays a larger role in this area. The third column in Table 1 indicates the amount of total healthcare spending, dedicated to pharmaceutical expenditure. The ratio between pharmaceutical spending and healthcare expenses reveals that in low-income countries, pharmaceutical investments represent a significant share, even reaching extremely very high values. This is since the costs of maintaining facilities and employees are cheaper than the expenses of medicines. Even though pharmaceutical spending is frequently a large portion of total healthcare spending, the per capita value is also quite low.

3.1.2 Underdeveloped Countries' Distribution System

Medicine, like any other product, requires a distribution chain to move from the producer to the consumer while keeping intact the characteristics of the product and possibly with as few transactions as possible, which only add to an increase in the final price. Both the public and private sectors are involved in the distribution chain.
Access to medications, as mentioned before, is a privilege of a few in underdeveloped nations, due to high prices, a lack of facilities, and a lack of public funding.
The final price of a drug is given by the following components:
- basic price
- transport and storage costs
- import tariffs
- taxes on value
- wholesale and retail margins
- remuneration of staff
- costs caused by stock losses or misbehaviour

The base price is the starting point from which the remaining components are calculated. It varies, sometimes significantly, from nation to nation, depending on market factors, procurement procedures, and patent law. Due to competition and safe sales, a medicine with high demand is likely to have a low price. Procurement procedures have a

considerable impact on pricing; as detailed further in this chapter, an effective management system may result in large savings.

The necessary pharmaceuticals can be ordered in set amounts or in estimations; the latter way is preferred since it allows to order a quantity that is near to that actually consumed. In fact, an issue that frequently occurs is that of a lack of medications, which forces them to resort to emergency orders.
To address these issues, orders must be based on estimations that roughly reflect the amount required. The country's financial insecurity might result in exchange-rate costs. Finally, patent legislation has an impact on the fundamental price: patent rights are not protected in all countries. Where it exists, the producer has the ability to set the monopoly price, which is the highest price that the market will be able to sustain
Transport costs include those for shipment from the manufacturer to the port of destination and from this point to the wholesaler, who may also be in another state and imposes additional expenses. Other costs related to transport are: packaging, storage, maintenance of certain storage conditions, port controls, insurance...etc.

The value-added tax (VAT) is another type of taxation that, like all other charges, is carried on to the final consumer. As federal taxes may exist, this tax intends to create additional revenue for the state as well as local governments. Wholesale and retail margins in developing countries are often very high, and the main reason for this is the lack of regulation and, even if there is regulation, the controls are insufficient.

Margins on pharmaceuticals can follow various mechanisms: a fixed percentage encourages the sale of expensive products; a decreasing percentage, on the other hand, tends to promote cheaper products; a set prescription margin reduces the incentive to prescribe expensive medications; a degressive margin encourages the prescription of generics. In some cases the high retail margin corresponds to discounts granted to certain customers, or for the purchase of large quantities. Discounts offered to certain consumers may correlate to a high retail margin or to the purchase of big volumes in some situations.

Therefore the State would have to carry out an active role in this within, taking part with politics of control of the margins and greater efficiency in the transport and the harbour services.

3.1.3 Drug Prices in Developing Countries

Drug prices are a very important variable to ensure access, especially when available treatments can avoid hospitalisation, when the cost of therapy is for the most part borne by the patient and the income of the patient requires to procure the good at the lowest possible price.
The cost of medications is a significant variable in ensuring access, particularly when available treatments can avoid a hospitalisation, and when the cost of therapy is carried principally by the patient, and the patient's financial situation necessitates seeking the best treatment at the lowest possible cost.

Increasingly, the importance of prices to ensure access to medicines is stressed, even for the half of the world's population living on less than USD 2 per day, but monitoring these prices is in fact a difficult task. The WHO claims that 95% of the medicines on their list of essential medicines are not protected by any patent rights; there is indeed sufficient competition for these drugs, such that prices are very low. The production of generic drugs takes place mostly in European or American countries, so there is the problem of shipping drugs to developing countries, whose costs can be low where there is a good system of infrastructure and large orders, but also considerably higher where deficiencies cause material and time losses.
In terms of the retail price of drugs, data is limited, owing to the difficulty in obtaining it. Because there is no structured and controlled distribution system, medicines can be sold through a variety of institutions. To determine the consumer price, interviews must be conducted, maybe at each type of distributor, in order to identify availability and, lastly, to trace the markups, which are entirely at the discretion of the subject participating in the sales chain.
The problem of prices is a very uncertain area even within each country. The level of prices can vary depending on the structure that dispenses them, the type of person who

needs it and who grants discounts, the geographical area and finally depending on whether it is a rural or urban area. Research is becoming more detailed and broader, but we are far from having a homogeneous picture of the situation.

3.1.4 Drug Price Surveys

Knowing the exact price of a medicine to the patient is difficult; it is often problematic to know it in the industrialised countries where there are efficient systems of regulation and price control, even more so complicated to detect it in the Sub-Saharan countries, where there are many obstacles, described above. However, in recent years, there has been an increase in the number of direct on-site investigations, interviewing pharmacies and public hospitals, conducted by health-related NGOs, mainly MSF (Médecins Sans Frontières) and HAI (Health Action International).

3.1.4.1 MSF Investigation in East Africa

MSF carried out a study in four East African nations in 2000: Ethiopia, Kenya, Tanzania, and Uganda. This investigation has the advantage of interviewing a large number of facilities (hospitals and pharmacies); the team was able to collect information from 9 pharmacies in Uganda, 10 in Ethiopia and Tanzania, and 16 in Kenya. The investigation covered public and private hospitals, as well as non-profit and for-profit pharmacies. There were 15 essential drugs identified, 8 of which are still patent protected. Unfortunately, the data available only cover four nations, among which Ethiopia was deprived of most of the drugs.

Only the data considered most relevant to this thesis were included in a summary table. Only pharmacies were considered among the many facilities investigated since they are the most prevalent, therefore it is easier for a patient to find a pharmacy rather than another institution, and to check if a patient genuinely has access to affordable medications without having to go to the public hospital. All the pharmaceuticals included in the investigation were considered, and the patent state was indicated, with the exception of Ethiopia, which was excluded owing to a lack of data; the price in the

pharmacy and the likely price of the generic were reported in each nation. This enabled the calculation of the percentage change in price between the minimum and maximum.

TABLE 2: SUMMARY DATA ON PRICES IN PHARMACIES

MEDICATION		MEDICAL USE	PATENT	AVERAGE PRICE PHARMACY			GENERIC PRICE			% SMALL TO LARGE MARGIN
				Kenya	Tanzania	Uganda	Kenya	Tanzania	Uganda	branded
Azithromycin	250mg	Trachoa Antibiotc Drug-resistant TB	Si	2,7	3,4	3		1,3		26
Ceftriaxone	250mg		No	8,8	10	15,7		7,5		78
Ceftriaxone	1mg	Fungal	No	-		-		9,4		
Ciprofloaxin	250mg	infection	No	2,4	3	3,1	4,4			29
Ciprofloaxin	500mg		No	4,8	3,4			0,21		41
Fluconazole	50mg	Fungal	Si	5,5		7,4	0,16			35
Fluconazole	150mg	infection	Si	-	23,1			0,24		
Amphotericin	50mg	Malaria	Bi	13		5,7	0,17			128
Mefloquine	250mg	Malaria	No	3,7	5,5			-		49
Artemether	50mg	ARV	No	0,64	0,88	0,58		2,5		52
Aciclovir	200mg	AIDS	No	2,7	2	2,3	1,2			35
Lamivudine+zidovudine		ARV	Si	6,2				-		
Didanosine	100mg	ARV	Si	2,1	1,9		2	3,1		11
Lamivudine	150mg	ARV	Si	3,1	3,4	2,7				26
Nevirapine	200mg	ARV	Si	8,7			1		0,59	
Stavudine	40mg	ARV	Si	5	5,1		0,58			2
Zidovudine	100mg		Si	1,3	2,3	1,2				92

Fonte: K.Bala e K.Sagoo “Patent and Prices”, 2000

The data shown in table 2 may lead to several observations. Firstly, we notice the high price of pharmaceuticals, which is expressed per unit of product in this study, but it is evident that if a cure prescribes the intake of several units, the total cost of therapy rapidly reaches extremely expensive levels, especially when compared to the per capita income of those nations. Secondly, despite the fact that these nations are geographically close to one another, their costs differ.

Prices of generic products, where available, have been included in the investigation, especially in Tanzania and Uganda. However, it should be noted that even with very low prices for generics, the price of the originals is not particularly affected; the first step,

therefore, is to check the availability of the generic drug in pharmacies, since, as noted above, often there is really no alternative to the original drug and patients are forced to buy branded medicines. Table 3 therefore gives the number of pharmacies where the original and generic drugs were found. It is recalled that the pharmacies interviewed in the three countries were 16 for Kenya, 10 for Tanzania and 9 for Uganda.

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TABLE 3: NUMBER OF PHARMACIES IN WHICH THE ORIGINAL AND GENERIC DRUGS WERE FOUND

MEDICATION	KENYA		TANZANIA		UGANDA	
	Original	Generic	Original	Generic	Original	Generic
Azithromycin 250 mg	16		1	5	5	
Ceftriaxone 250mg	14		1	1		1
Ceftriaxone 1mg						
Ciprofloxacin 250mg	16			4	1	6
Ciprofloxacin 500mg	1		4			
Fluconazole 50mg		17	1	3		
Fluconazole 150mg	7					2
Amphotericin B 50mg		14	5	10	7	
Mefloquine 250mg	11					
Artemether 50mg			8		8	7
Aciclovir 200mg	16					
Lamivudine+zidovudine			4		4	
Didanosine 100mg	10					8
Lamivudine 150mg	11		1			
Nevirapine 200mg					1	
stavudine 40 mg	11		4			
Zidovudine 100m	6					
	1		1			
	13		3		2	

Fonte: K.Myhr, MScPharm

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It can be verified that the generic, when present on the market, is available as much as the original, indeed in some cases it has been found more often the generic than the original. Yet the wide availability of the generic version has not affected the price of the original. At this point, the logical conclusion is that the market for branded medications is unaffected by generic competition, for many reasons. The most plausible hypothesis

appears to be linked to the trust that doctors and patients place in branded products, considered to be of higher quality than the generic version; in Africa, the smuggling market is prevalent. It may also involve medications and the fear that patients will come across ineffective or even harmful to health, prompting them to prefer the original drug. Given this condition, pharmaceutical companies have no motivation to lower their prices; they know that customers prefer their goods and that those who do not buy them simply do not have the financial capability.

However, another problem emerges from the data. Only two generics were discovered in Kenya[20], in that the government adopted legislation to protect intellectual property in line with the TRIPS Agreement, yet the price of the original is the lowest among the three nations examined for six out of 13 medications. This desire to comply with patent rights may have resulted in reduced costs for original medications.

Kenya's lower prices can also be justified with another hypothesis. Looking again at Table 3 it can be noted, first, that in Kenya drugs are widely available in pharmacies, in fact the availability is around 100%. Then we proceeded by comparing the availability with the price of the drug and it was found that precisely the drugs that in Table 2 have the lower price, were found in most pharmacies.

The drugs with the lowest price in Kenya were available in 11, 14, 16 pharmacies; while in the case of Amphotericin B, for the same number of pharmacies, Uganda prevailed with a price of 5,7 $ against 13 $. Now, we do not know exactly where these pharmacies are located in the territory, but the number of pharmacies correlated with the drug - price can make us assume that the greater the number of facilities that have the drug, the greater the competition to the distribution and the lower the price. This is a fact that does not depend on the initial price of the manufacturer, but rather on competition between pharmacies. However, it is known that prices in Kenya are set at national level by means of bi-monthly lists, so that profit margins should also be fixed; but it is also known that in many sub-Saharan countries there are no serious controls on the activity of these operators, so often the law is circumvented to get more profits. It is therefore considered that in the absence of such many pharmacies, competition would have been lower and prices higher.

[20] Kenya, at the time of the investigation, was the only country that guaranteed patent protection

The only case in which Kenya did not present the lower price concerns Aciclovir, which was also available in 16 pharmacies; Tanzania prevailed, in which Aciclovir was found in only 4 pharmacies but the generic version in 10, so it is possible that in this case the competition of the generic has prevailed over trust in the brand.

3.1.4.2 Database of HAI

Since 2001, Health Action International has used a new approach for detecting medication prices in poor nations that is innovative and beneficial for gaining a more accurate knowledge of the amount of them in various countries throughout the world.
The most recent studies have in common the fact that they have attempted to detect prices in the greatest number of structures, public and private, profit and non-profit, to investigate the mark-ups that are added during the journey from the manufacturer to the consumer, and to express a measure of drug availability in various facilities.

As for prices, it is necessary to explain the method used, as they are not simply expressed in dollars; the value that is in the database is called "Median Price Ratio" (MPR) which, according to the definition provided by the website, is the median price per unit of product expressed in local currency, compared to the international reference price, also converted into local currency. At this point it is also necessary to define what is meant by international reference price: an American organisation, Management Science for Health (MSH), draws up every year a guide to the prices of drugs included in the list of essential drugs of the WHO, listing prices of the main supply agencies[21]. The database[22] that reports these prices at source, summarises for each drug the median price, depending on the number of agencies that have the drug: this is the international reference price used by HAI. The lower the MPR, (therefore close to the wholesale price of international agencies) the more efficient the system and the lower the final prices. The price ratio of

[21] Major distribution agencies include Action Medeor, Durbin PLC (which also delivers to doctors, pharmacies...etc), ECHO International and IDA Foundation. The list prices of these agencies are usually ex-stock sellers, so do not include any charges for transport, insurance and cargo. In addition, drugs are often offered in "maxi" packs, which reduces the price per unit, but distorts the comparison with the price per unit of smaller packs.
[22] http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English

the drug/international reference price allows to have easily comparable values, because they are not affected by the real price of a drug, which may be greater for certain drugs and lower for others: the price of the drug found in the health facilities is, for all the selected countries, compared to a single value.

The interviews so far included in the database are 13, each conducted in short periods of time between 2001 and 2004; however, for the purpose of this work, It was decided to select only those surveys which were drawn up during the same period and in particular those relating to the 2001 international reference prices, in order to obtain data based on the same unit of measurement. Six countries were selected, with a particular focus on Kenya and South Africa. The other countries considered are Brazil, the Philippines, Peru, South Africa and Sri Lanka.

Before proceeding with the data analysis, it is considered useful to discuss some investigation features (number of structures interviewed) and national health system characteristics, which differ significantly from country to country.

The survey in Kenya involved 26 pharmacies, in public hospitals the treatment is free, but there is no information on the availability of drugs, which is also low for the private sector (32.7% for the originals).

In South Africa, in the state of KwaZulu Natal, 18 pharmacies and 2 private hospitals were interviewed, which had a high availability of the original drugs, 75%; there is no data on the public sector apart from the fact that the treatments are administered free of charge.

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TABLE 4: PER CAPITA INCOME OF SELECTED COUNTRIES

COUNTRY	**INCOME ($)**
Brazil	3090
Kenya	350
Perù	1970
Filippine	1030
Sud Africa	2740
Sri Lanka	840

Source: World Bank, 200

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Although it is already known that drug prices are not related to the per capita income of the population and that per capita income does not take into account the real distribution of wealth in the country, it was considered useful to report these data, to get a basic idea of the country's position in the international framework. A first relevant comparison, given the form of the data provided, is the average of the MPR for each nation and for the two categories of medications considered, original and generic. Table 5 contains the data.

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TABLE 5: ARITHMETIC AVERAGE OF THE MPR

	ORIGINAL	GENERIC
Brazile	28,897	**17,53**
Kenya	28,667	**18,391**
Peru'	36,264	**5,185**
Filippine	44,037	**21,78**
Sud Africa	45,78	**25,46**
Sri Lanka	5,426	**1,0113**

Source: http://www.haiweb.org/medicineprices/surveys.php

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The values in this table simply indicate how much, on average, the prices of medicines in a country are higher than the international reference price for originals and generics respectively. It is generally assumed that, if prices in one country are high, they are high for all medicines without distinction, which means that prices are uniformly higher than in other countries.

The graph compares the original medicine pricing in three countries with the biggest variation: South Africa, Kenya, and Peru. According to the data, some medicine costs are in accordance with the international reference price, while others are entirely out of control. This is due to a variety of factors, including distinct suppliers for each medicine, market characteristics for one product over another, quantity of supply over demand,

patent protection, and the presence of the generic. The question is, however, why this disparity: if some pharmaceuticals can be obtained at reasonable prices, why not the others? This huge fluctuation in values appears unreasonable, and although it may distort the average value, it is still considered to use the average as a summary indicator, because all drugs are potentially needed. Moreover, the other countries, except for Sri Lanka, also have a good variability, but in general prices are lower.

Reading Table 5, the focus must be on the values of Sri Lanka, which for generics are even close to one, which means that on average prices correspond to those that international agencies offer wholesale, and what is most surprising is that the international reference price does not include the various expenses that the shipment involves. It is therefore deduced that the pharmaceutical market in Sri Lanka is very efficient, perhaps because of the feature mentioned above, which concerns the simultaneous presence of private and public pharmacies and consequently a high level of competition.

South Africa, on the other hand, is the country with the higher prices, which are on average 45.78 and 25.46 times higher than the international reference price for original and generic medicines respectively. The problem of relatively high prices in South Africa compared with other countries and also with respect to the level of income, which is, moreover, unevenly distributed among the population, has already arisen on other occasions and these data can only confirm the situation.

Finally, a rather curious case concerns Kenya, where generic drugs are available at remarkably low prices, but the original drugs remain at very high levels. It is considered logical to link this case to the speech made in the previous paragraph, in which it was found that in some countries of Africa the presence of even large quantities of the generic does not undermine the position of the original producer, which consequently persists in charging much higher prices.

However, the data in Table 5 are not considered adequate for a measure of the level of competition, as some drugs are only available in the generic version, others only in the original version; by them it is not possible to determine whether there is direct competition between medicines.

For this reason, in a second step of the analysis we proceeded to select those original drugs that see the presence of the generic on the market, and we calculated the average discount that patients get from buying generic drugs rather than originals. However, the data in Table 5 are not considered adequate for determining the level of competition because some drugs are only available in generic form, while others only in the original form; thus, it is impossible to determine whether there is direct competition between medicines.

4 Making Medicines in Africa: An Historical Political Economy Overview

4.1 Pharmaceuticals in Kenya: The Evolution of Technological Capabilities

4.1.1 Kenya: creating the dominant East African producer

Kenya's pharmaceutical sector is the strongest producer of pharmaceuticals in the East African region, and is upgrading to more demanding technological capabilities. In addition to the standard generic products in the dosage forms of tablets, capsules, creams and syrups, the industry in Kenya includes three firms producing injectable infusions (small and large volume parenteral preparations) and ophthalmic formulations. One firm (Universal) has achieved WHO prequalification for one of its products, allowing the firm to tender for donor contracts and also providing an indicator of the firm's technical capabilities and standards.

A further measure of the strength of Kenya-based pharmaceutical production is its export success, which accelerated from about 2002. Kenyan pharmaceutical producers' main export destinations are in the COMESA region: the Common Market for Eastern and Southern Africa, which does not include South Africa or Tanzania.

With supportive government policies, Kenya should be able to exploit effectively the integration of East African and Southern African markets to expand its role as one of the medicines production 'hubs' in sub-Saharan Africa. This sections discusses the industrial challenges in depth.

4.1.2 Pharmaceuticals in Kenya: The Evolution of Technological Capabilities

A 2015 Business Monitor report on pharmaceutical manufacturing in Kenya states that the country hosts the largest pharmaceutical industrial base in East Africa. The report also sees a bright future as a 'potential base for export across East Africa' (BMI Research, 2015).

The qualities of Kenyan economic and industrial systems, which are the product of its economic history, determine the characteristics of local medicine production.

The features of the local production of medicines are shaped by the characteristics of the Kenyan economic and industrial systems, which in turn are the product of its economic history. To examine this structuring, this chapter first introduces and then applies an evolutionary economic view of industrial capacities, emphasizing on technical capabilities at the company and industrial system levels, as well as their origins and evolution. This industrial analysis framework is typically used to examine the development of a technologically demanding industry, pharmaceuticals, in relation to the industrial and economic context of a low-income country like Kenya.

Moreover, this chapter looks more into how Kenya's pharmaceutical industry has grown on this framework, as well as the opportunities that have emerged as markets have become more liberalised and competitive.

4.1.3 The evolution of Kenya's pharmaceutical industry in the context of post-colonial industrialization

The pharmaceutical sector in Kenya is shaped by the country's larger economic and industrial history. Kenya's post-independence industrial history may be divided into three phases based on the policy regimes that were adopted: the early years of import substitution industrialization (ISI), until the 1970s; the liberalization and gradual opening up of the economy in the 1980s and 1990s; and the new millennium (Chege, Ngui and Kimiyu, 2014).

In the Kenyan case, local producers were shielded from foreign competition in manufactures in a variety of ways. High tariffs, even reaching 100% of the goods' value, and quotas were imposed on imported manufactures, which were also charged higher rail fares, with the result that their prices were high for Kenyan consumers. The Kenyan government also explicitly welcomed foreign-owned firms who set up production facilities in the country, as they contributed to the domestic industrial development. The large weight of FDI in Kenyan industry of the colonial period is also typical of the early years of independence, when it even reached half of industrial output (Maxon, 1992).

Manufacturing of consumer goods for the local market expanded rapidly in the early 1970s, and there was diversification into upstream supplier industries such as plastics. In this 1970s period, pharmaceutical manufacturing expanded, benefitting from the industrial protection, and also from an active government policy to promote investment and

technological upgrading. Laboratories & Allied was incorporated in 1970. The government established the Industrial and Commercial Development Corporation (ICDC) to promote the inclusion of local people in industry by providing development finance and technical assistance. ICDC helped to develop pharmaceutical production in this period through parastatal joint ventures (Research Fellow in Regenerative Medicine, University of Edinburgh, United Kingdom).

Kenya was forced to take out a loan from the World Bank in 1980, which included structural adjustment requirements. This marked the beginning of the phase of liberalisation and structural adjustment policies that occurred throughout sub-Saharan Africa in the mid-1980s and 1990s, as well as the beginning of a shift to export promotion. The growing liberalisation of local markets produced competition, which harmed local manufacturing activities. Foreign currency shortages contributed to the decline of domestic industry by making it impossible for enterprises to buy foreign inputs and equipment, which had a negative impact on capacity utilisation and hence productivity. After an economic crisis at the beginning of the 1990s, liberalisation and export promotion accelerated with the creation of Export Promotion Zones (EPZs), participation in the Common Market for Eastern and Southern Africa (COMESA) and the East Africa Community (EAC), and the removal of price controls in 1994. Export promotion and international competition, however, had little impact on pharmaceuticals in that period. More important was a push in the 1990s to 'buy local', aiming, for example to ensure that basic medicines kits should be 50% local products (Wamae and Kariuki Kungu, 2014).

During these years, most of the foreign MNCs (Multinational corporations) also ceased to produce in Kenya as they reorganised their supply chains globally in the light of competition from China and India to find cheaper locations for production. The development of Kenya's pharmaceutical industry suggests that ISI (Import substitution industrialization) policies were important to build an initial industrial base. Previous analyses of industrialization have argued the ISI policies followed by careful liberalisation and export promotion might be useful to promote industrialization (see, e.g., Athreye, 2004, for the Indian software industry).

4.1.4 The Kenyan pharmaceutical industry and its market position

In historical studies of industrialization in Kenya, the pharmaceutical sector is rarely mentioned as it traditionally accounted for a very small share of industrial output. However, recently its status has been increasingly recognized. For example, pharmaceuticals are mentioned as one of the eighteen strategic sectors in the National Industrialization Policy 2011–15 (Ministry of Industrialization, 2010). Kenyan local manufacturers of medicines have shown great resilience during the years of economic difficulties and are now embarked on a process of growth and technological upgrading that, if successful, can establish them as a major player in the East African market for medicines.

As Figure 1 shows, in that period total production of tablets, capsules, liquid preparations for oral use and creams/ointments alone increased from US$34.1 million to US$154 million.

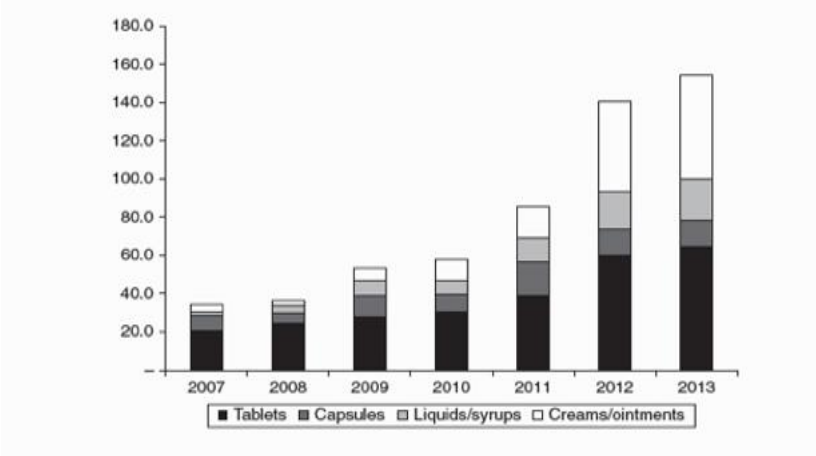

Figure 1. Local production of non-parenteral medicines in Kenya by type of product, 2007–13 (US$ million)"

The graph also demonstrates how product composition has evolved over time, with creams and ointments becoming more common, while all product categories have gradually grown with the probable exception of capsules.

Kenya has also seen strong growth in its pharmaceutical exports in the new millennium, especially since 2002 as mentioned before. Exports started growing around 1992–93 thanks to the 'buy local' push, which promoted the expansion of local manufacturing. These years

also saw a wave of divestments of production activities from foreign-owned companies that carried on in the new millennium as Kenya's industrial environment deteriorated and MNC (Multinational corporation) producers moved out of Kenya to lower cost platforms. By 2014, only one MNC was still manufacturing in Kenya – GSK. Otherwise, pharmaceutical firms in Kenya are currently mainly locally owned (UNIDO, 2010).

In the new millennium the Kenyan domestic medicines market has been hit by more global competition, notably from South Asia. A key development for the pharmaceutical industry has been the large-scale movement of donors into supplying medicines for malaria, TB and especially HIV/AIDS. This has been a strong influence on the domestic market and pharmaceutical policies. The arrival of the large donors was, however, somewhat later and more patchy in Kenya than in some neighbouring countries: PEPFAR, for example, the main US programme for funding HIV/AIDS medication, began to operate in Kenya only in 2008, and Kenya received no funding under Rounds 8 and 9 of the Global Fund financing (UNIDO, 2010: 41).

The production capabilities of the Kenyan industry were confirmed during this period by the companies' role in the campaigning that led to the 2001 government decision to allow compulsory licensing of generic production of HIV/AIDS medicines, and the subsequent issuing of voluntary licences (UNIDO, 2010).

4.1.5 Technological capabilities and sectoral systems of innovation

The previous sections have demonstrated that Kenyan pharmaceutical firms are experiencing a period of expansion. However, businesses confront challenges from low-cost imports as well as the necessity to continually improve their technology in order to compete globally, meet more rigorous technical requirements, and effectively exploit new market prospects. The extent to which local producers can develop their technological capabilities is thus an important aspect in the future prospects of the Kenyan pharmaceutical sector.

The notion of technological capabilities, which has now entered the mainstream analysis of industrial development, can be traced back to the work of evolutionary economists such as Richard Nelson, Sydney Winter, Christopher Freeman and Giovanni Dosi (Dosi et al., 1988; Nelson and Winter, 1982). Evolutionary economics began as a critique of economics' main theoretical framework, the neoclassical approach. The criticism came from the

conclusion that neoclassical analysis techniques were unsuitable for studying technological and industrial development.

Neoclassical economics focuses on the working of the price mechanism in the coordination of economic activity but makes strong and unrealistic assumptions about the nature of technological knowledge and the way firms (and, in general, other economic agents) operate.

However, evolutionary economists believe that much technical knowledge is implicit and hence difficult to explain. Effective use of technology requires the processing of publicly accessible technical information using know-how and skills that are not only costly to acquire but also vary among enterprises, sectors, and nations.

Technological capabilities, therefore, are the organizational skills that enable firms to make effective use of technologies, including the ability to adapt them, improve them and even develop radically new products and processes. The technological capabilities of the Kenyan domestic pharmaceutical sector are analysed by looking at various dimensions of the production system in which local manufacturers of pharmaceutical operate.

4.1.6 Industrial structure

Local manufacturing of pharmaceuticals in Kenya is dominated by locally owned firms. In 2014 there were 39 local manufacturing firms with products registered with the Pharmaceuticals and Poisons Board (PPB), the agency that regulates the manufacture and trading of medicines in Kenya (UNIDO, 2010). Of these, 34 produced medicines for human consumption, whilst at least five firms produced animal health products. Of the 34 firms, only one producer is a foreign-owned MNC, GSK East Africa, which has not followed the exodus of other MNCs. Although MNCs dominated the local production of pharmaceuticals in Kenya in the 1990s, because of the unattractive economic conditions in Kenya in the 1990s and changes in global supply chains, most of them have moved production facilities to lower cost locations and are only present in Kenya for activities such as marketing and clinical studies (Wamae and Kariuki Kungu, 2014).

However, government policy has provided further incentives for domestic manufacture by removing import fees and taxes from inputs to pharmaceutical products, such as APIs, excipients and packaging materials.

The situation, however, changed in 2013 when the new VAT act reintroduced taxation for pharmaceutical inputs and only exempted finished products. This decision made locally produced medicines up to 22% more expensive, and the industry put pressure on the government to reverse the decision. This happened in the 2014 Act, but there are still some unresolved issues that are worrying local manufacturers (Wamae et al., 2014).

Studies of the Kenyan supply medicines chain show that Kenya has high margins for distributions, which raise the final price of the medicines to users in spite of fairly low manufacturing costs, in comparison to countries, such as Brazil, India, Indonesia, Kenya, Netherlands, Russia and South Africa. The study shows that the percentage of distribution costs is clearly highest in Kenya (see IMS Institute for Healthcare Informatics, 2014: 11). The high margins are a sign of the market power enjoyed by private distributors, who have access to cheap imports, mainly from India.

4.1.7 Productivity, capacity utilisation and cost efficiency

Unfortunately, it is too difficult to obtain a direct measure of productivity for the various manufacturers, but it is well known that capacity utilisation is an important determinant of productivity. Firms that only operate at a low level of capacity utilisation are less efficient and can only achieve relatively low levels of productivity (see IMS Institute for Healthcare Informatics, 2014).

4.1.8 Human resources and the educational system

Successful industrial production requires a range of different skills. Local universities, such as Jomo Kenyatta University of Agriculture and Technology, Mount Kenya University and the University of Nairobi, provide graduates with good-quality basic skills and training in pharmacy, engineering and chemistry (UNIDO, 2012). Top polytechnics such as the Kenya Medical Training College are good sources for mid-level training. Employees also use foreign universities, for example in the UK, Germany, and India. All firms also have compulsory training in-house. However, the internal education system cannot meet all industry requirements, especially as upgrading is needed.

Official reviews (UNIDO, 2012) and interviews suggest that there is a scarcity of pharmacists specialised in industrial pharmacy. Although the school system has a high

literacy rate and produces well-trained clinical pharmacists, newly certified professionals require considerable training in industrial elements of drug manufacture, including specific training in industrial quality assurance. One critical difficulty is that the teachers were initially educated in clinical pharmacy, hence Kenya does not have a long tradition of industrial pharmacy.

University graduates have a good training in basic skills and theory, but many firms make use of training programmes run both internally and externally by international organizations, such as GIZ, Action Medeor and UNIDO. The latter sponsors popular courses such as the industrial pharmacy advanced training course run in Tanzania at the Kilimanjaro School of Pharmacy with the support of US universities (UNIDO, 2015).

Firms use some local training institutions, both public, such as the Kenya Medical Research Institute (KEMRI) and the Pharmacy and Poisons Board (PPB), and private. For advanced skills, however, they need to bring in experts from abroad, usually from India but also from other countries.

Finally, firms may use their informal networks to transfer personnel abroad for training, with India being a favourite destination due to the importance of the Indian pharmaceutical sector. So local manufacturers appear to be able to rely on a solid internal supply of skills, although at a very low level, as well as access global expertise, despite the latter being subject to intensive scrutiny due to its high prices.

4.1.9 Equipment and inputs

The shallow level of the Kenyan industrial sector is an important factor when inputs to production and equipment are considered. Kenya's industry is one of the most developed in East Africa, and local producers can find local suppliers for basic inputs including packaging, with the exception of some more advanced packaging for sterile products, which is procured abroad, for example from China. Some more technologically complex packaging, such as over-pouches for injectables, used to be imported but are now produced locally (Making Medicines in Africa, Maureen Mackintosh).

Raw materials for production are mainly imported, due to the lack of producers of APIs Active pharmaceutical ingredients (APIs) and excipients. This dependence on imports is an important issue because it generates possible shortages which might influence production capacity, and additional costs even though pharmaceutical inputs are supposed

to be exempted from duties. Kenya does not have a developed industrial machinery sector, so the main machinery is imported from international suppliers. A popular source of equipment for pharmaceutical production is India followed by China. India's machines are significantly cheaper than those from industrialized countries and basically do the work well enough for tasks that do not require a high level of technological sophistication. Europe (especially Germany and Italy) and other high-income countries are the sources of more advanced and reliable machinery. The choice of suppliers is sometimes dictated by financial considerations: higher-quality machinery might be not only more efficient but also more profitable in the long run. Companies, however, lack the resources for a high upfront investment in European machinery, in spite of the fact that the financial sector in Kenya is the most developed in East Africa. Finally the dependence on imports of machinery creates more costs for local firms.

4.1.10 Knowledge flows, linkage capabilities and innovation

As previously said above, capacities at the industry level are determined not only by the capabilities of various economic actors, such as manufacturers, but also by the effectiveness with which the many components of the industrial system interact and promote information flows. As a result, this section digs further into the system's information flows and how they impact the accumulation of capabilities inside firms. Medicine producers develop their capabilities by acquiring knowledge from the external environment and through experience accumulated through a process of learning-by-doing over time. An additional input to the firms' capabilities comes from the education and training activities of its workers, as discussed above. Firms, however, can step up their accumulation of knowledge by explicitly investing in learning. Kenyan enterprises have been able to tap into their suppliers' knowledge networks in order to locate foreign specialists to recruit, appropriate training programmes, and foreign organisations where they may send their personnel to learn more about modern industrial technology since they use foreign suppliers. Other typical methods through which businesses obtain relevant knowledge include exhibitions (including those held internationally), websites, participation in professional organisations, and attendance at conferences.

4.1.11 Licensing and joint ventures: the role of government policy

As mentioned in the preceding section, technical capabilities accumulate over time, and current capabilities are influenced by past events. Because technological knowledge is cumulative, policy initiatives can have a long-term influence on the capacity of enterprises and sectors. In Kenya, there are two examples of policy interventions that can be said to have helped the development of technological capabilities in the industry: compulsory licencing provisions in Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiations, and the policy of forming parastatal joint ventures with foreign MNCs to develop local capabilities based on foreign technology.

In the case of licensing of foreign technology, Kenya campaigned strongly during the trade negotiations that led to the TRIPS agreement to be able to carry out compulsory licensing for some essential medicines. Compulsory licensing means that governments can issue licenses to manufacture medicines that are still protected by patents at more affordable prices than those set by foreign pharmaceutical companies that hold the patents, without receiving the latter's consent. Although in practice there has been no compulsory licensing in Kenya, it can be argued that the threat of compulsory licensing has enabled local firms to reach good licensing agreements with foreign MNCs. According to Garwood (2007), 'Kenya has never issued a compulsory license, but came close to in 2004 before the German pharmaceutical major Boehringer Ingelheim agreed to enter into a voluntary license agreement with Kenyan drug firm Cosmos to produce generic versions of its patented anti-AIDS drug nevirapine'.

4.2 Industrial Policies and Health Needs: The case of South Africa

Despite the interest in the African pharmaceutical market, there are constraints and challenges that continue to affect access to medicines. One of the key constraints is the high prices of medicines. In the private sector, wholesale and retail mark-ups have been found to range from 2% to 380% and from 10% to 552%, respectively (Cameron et al., 2011). A later study found wholesaler mark-ups between 25% and 50% (IMS Health, 2014a; 2014b), and retail mark-ups between 25% and 500% (Rosen and Rickwood, 2014). Local manufacturers

and importers alike have expressed concern over the high mark-ups in the distribution chain, as the exorbitant prices are believed to limit patients' access and sales.

All African countries are dealing with the problem of excessive drug prices. With the growing enthusiasm for creating local pharmaceutical companies, policymakers will be forced to confront the issue of drug costs and how to control them. African policymakers are also fully aware of strategies used by other nations throughout the world in rising health-care expenses, particularly pharmaceutical spending. Although price controls are important policy tools, they are very contested. The South African experience with pharmaceutical price restrictions may thus be a good case study to influence the initiatives of other African governments.

This section discusses the South African experience with single exit price (SEP) legislation, which were adopted to address these distortions and to replace mark-up-based retail pricing schemes with fixed professional fees, thereby lowering patient costs.

4.2.1 Pharmaceutical price control options

Governments have moved to control pricing for many reasons. First, the inventive pharmaceutical business has historically been dominated by monopolies, producing a tendency to overprice goods. Medicines are also distinct from other consumer items in that patients are frequently price-incentived, owing to the fact that the doctor prescribes and a third party pays for the drugs. Moreover, many consumers and health care professionals associate a higher-priced product with excellence and a lower-priced product with inferiority, resulting to prescribe, distribute, or request high-priced items. The challenge for governments therefore is how to institute proper controls to ensure that medicines are priced fairly and that access is not constrained by high prices (Council for Medical Schemes, 2014).

The literature on pharmaceutical price controls identifies three distinct ways in which expenditure can be controlled: direct controls on the prices of medicines across various levels in the distribution chain; through demand-side measures including financial and reimbursement systems; and finally, by influencing demand through the implementation of demand-side measures (Maureen Mackintosh. "Making Medicines in Africa").

4.2.2 The basis of the South African price control regime

When the first democratic government in South Africa came into power in April 1994, it inherited a two-tier health care system (private and public) reflective of the country's divided history. These two tiers have widely differing resources and access medicines via different channels. The private health care tier is a well-resourced private insurance-based world-class platform which serves an estimated 15% of the population (Council for Medical Schemes, 2014). The private pharmaceutical market is valued at $4.1 billion (IMS Health, 2014b) and is supplied with medicines by about 130 manufacturers and importers supplying 5,000 product lines.

The second tier, the public sector health care system, serves the remaining 85% of the population. Public sector supplies are obtained through tenders administered by the Central Procurement Unit of the Department of Health. It is supplied with 2,400 product lines by an estimated 90 manufacturers and importers, at an estimated value of $1 billion a year in 2014 (IMS Health, 2014b).

However apart from these deep divisions, the democratic government faced spiralling health-care costs and a more and more exclusionary health-care system in which those who served the poor and marginalised paid more for medicines than those who served the affluent areas, who were much more likely to benefit from price and volume discounts, rebates, bonuses, and other incentives. Historically, drug pricing was left to market forces, so companies were allowed to set their own prices, give incentives and offers, discounts and rebates. As a result, the government decided to interfere to correct these inaccuracies.

Despite the large literature on pharmaceutical price controls in highly developed markets with well-developed health insurance schemes and universal coverage (Rietveld and Haaijer-Ruskamp, 2002), there was little from the developing world with similar health care systems to South Africa with a significant portion of patients without health care insurance and with considerable out-of-pocket expenditure on health care and medicines.

4.2.3 Constitutional enablers of the National Drug Policy

On 8 May 1996, the democratically elected parliament adopted the new Constitution of the Republic of South Africa[23]. The Constitution of the Republic of South African – 'Everyone has the right to have access to – a) health care services, including reproductive health care'. Section 27 (1) (b) of the Constitution further mandates the state to, 'take reasonable legislative and other measures, within its available "resources to achieve the progressive realisation of the right'."

This enshrined a Bill of Rights. Section 27 underpinned the legislative and regulatory processes that would follow in reforming the health sector; it read:

Section 27 (1) (a); everyone has the right to have access to healthcare services, including reproductive health.

Section 27 (2): the state must take all reasonable legislative and other measures within its available resources, to achieve the progressive realisation of each of these rights.

Informed by this constitutional provision, and aware of the need to address historical disparities of the past, create a new and equitable health care system with universal access to health care for all, and ensure the progressive realisation of Section 27, the government introduced a series of policy papers that would drive far-reaching regulatory and legislative reforms. The most significant was the 1996 National Drug Policy (NDP). The NDP had far-reaching consequences, serving as the foundation for the Single Exit Price (SEP) legislation discussed below.

4.2.4 National Drug Policy

The National Development Plan (NDP) (Department of Health, 1996) aimed generally at enhancing access to safe, cheap quality medications for all South African countries, and it provided the foundation for all following legislative and regulatory changes and adjustments.

[23] The Constitution of the Republic of South African – 'Everyone has the right to have access to – a) health care services, including reproductive health care'. Section 27 (1) (b) of the Constitution further mandates the state to, 'take reasonable legislative and other measures, within its available resources to achieve the progressive realisation of the right'.

Specifically, the NDP's objective was to promote the availability of safe and effective drugs at the lowest possible cost'.

4.2.5 Setting the regulations

The Minister of Health established a pricing committee comprised of representatives from the Departments of Trade and Industry, Finance, and the Competition Commission. There were pharmacists, attorneys, health economists, pharmaco-economists, academics, and consumer advocates on the group, but no industry representatives.

Their aim was to develop a new system in the price structure of all prescription and over-the-counter medications. The committee would also establish laws for logistics and dispensing costs, worldwide pharmaceutical benchmarking, and pharmacoeconomic assessment of drugs.

Moreover, the government stated that, when fully implemented, it expected the SEP (The single exit price) regulations to reduce the prices of medicines by 40–70%. In line with the regulations, effective 2 August 2004 and for a year thereafter, the price of medicines would not be higher than 50% of the 'Blue Book'[24] manufacturer net price.

The Blue Book was a well-known industry journal that provided independent and reliable price lists to the pharmaceutical and health care industries. The government said that the manufacturer net price given in the Blue Book was exaggerated to account for the industry's complex systems of bonuses, rebates, and other incentives, allowing retail chains to obtain pharmaceuticals for less than 50% of the listed Blue Book price.

The SEP[25] regulation 8 allowed for a manufacturer to set their single exit price, which could only be raised once on an annual basis, whilst temporary price reductions were allowed as often as the manufacturer wanted to make them for competitive reasons. The SEP could be increased only once a year based on a predetermined formula that incorporated, among

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[24] The term 'blue book' is used broadly for all Parliamentary papers, i.e., all papers published by Government and presented to Parliament. The annual Blue books of the Colonies were key publications. . https://libguides.lib.uct.ac.za/c.php?g=434393&p=2978215

25 In order to introduce transparency in the private market the government introduced the Single Exit Price (SEP) for medicines in 2004, for all prescription medicines, comprising of a fixed ex-factory price with a logistics fee component (and value added tax) for medicines sold to all purchasers other than the State.

others, the Consumer Price Index (CPI) and Producer Price Index (PPI) for the preceding year; changes in the rates of foreign exchange and purchasing power parity; and the need to ensure the availability, affordability and quality of medicines. The currencies considered are the US Dollar and the Euro, because most South African pharmaceutical companies purchase products from abroad with these two currencies.

The final increase as per formula is calculated as follows:

API Formula = 70% CPI (historical) + 15% (Rand/Dollar variance) + 15% (Rand/Euro variance)

The exchange rate split of 15% US$ and 15% Euro was based on data provided by the Department of Trade and Industry and data on pharmaceutical imports.

Although this formula has been applied from the beginning, the actual price increases granted by the MoH (**Ministry of Health)** have displayed a degree of discretion, and the timing has often been delayed, in some cases by up to five months. Manufacturers can also apply for increases above the formula-based increases, in order to assist manufacturers and importers to compensate for exchange-rate-related increases in the prices of production inputs or finished products imported from principals overseas (Making Medicines in Africa, Maureen Mackintosh).

Finally, the Director General of the Department of Health could inform the public if the single exit price of a medicine was unreasonable. Manufacturers and importers were required to inform the Director General six months before the registration of a medicine the intended SEP, the countries where the product was sold and how much it was selling for, the costs of manufacturing, and the marketing and selling costs of the product.

At inception, the regulations stipulated the maximum professional fees that could be added to the single exit price by various players in the distribution chain (Making Medicines in Africa, Maureen Mackintosh).

4.2.6 SEP impact on manufacturers and access to medicines

It is accepted internationally that the entry of generics significantly widens access to medicines, and the size (volume) of the market often expands after patent expiry. The impact

of the SEP regime on access to medicines is an area that still requires more and more investigation.

The reference prices are normally set with the first generic entrants and often undergo revisions with further entry. In certain instances, the revisions have been quite dramatic, leading to wholesale price decreases, further lowering the price of the drug and indirectly promoting access. The case of simvastatin is instructive. Simvastatin is highly genericized, with the first generic product launched in 2002 by Adcock Ingram. Adcock remained the clear market leader despite other generic alternatives. In 2009, Michol, a new simvastatin generic entrant, came in at a very low SEP, and as a consequence the prices of a pack of 30 simvastatin tablets dropped from over R120 to around R25. Arguably, the effect of this would have been to increase access by patients, especially those who pay out of pocket for package deals that include consultation fees and medicines from family practitioners.

The impact of the SEP has also come through in capping prices through private medical schemes' reference pricing systems. All the private medical insurance schemes have their own reference pricing systems to set the maximum price a scheme will pay for a generic drug. The effect has been to force newly launched generics to price below the reference price. Similarly, if, for competitive reasons, a generic manufacturer drops prices drastically and sets a new reference price, other companies are forced to follow suit or face the prospect of co-payments, which will deter patients.

Conclusion

The aim of this work is to analyse the various aspects of the problem of access to medicines in sub-Saharan African countries. In this regard, the thesis was introduced by a chapter on the typical pathological situation in these countries, which, as is well known, is influenced, and aggravated by the multiple problems that afflict these areas of the world. In this context, it was first deemed necessary to emphasise the fundamental right to health for all citizens of the world, who find themselves at the root of often complicated, inefficient, and unfair mechanisms.

The first chapter therefore aimed to illustrate the current situation in access to medicines, and then to identify and analyse the problems that stand in the way of the effective realisation of this right.

The second chapter was dedicated to analysing the discipline of patent protection, which is increasingly seen as one of the major obstacles to access to medicines in sub-Saharan countries. The purpose of patent law is to protect a discovery that is the result of intensive research from the possibility that an imitator could reproduce the drug and thus appropriate the profits; the law protects the interest of those who have invested time and money in research to incentivise investment in innovative activities. On the other hand, in doing so, the patent right grants a company market exclusivity and thus monopoly power. It is clear, therefore, that the regulation of patent rights significantly affects the global pharmaceutical market and prices. As a result, significant attention has been given in this article to treaties and agreements governing patent rights, but above all, the divergence of interests that characterised the negotiations has been highlighted, and the perspectives of the major parties engaged have been presented.

The third chapter went into more detail on what is the subject of this thesis: access to medicines. It is well known that access to medicines can be influenced by several factors: availability, quality, rational use, and price. Given the economic nature of the research, the focus was on price levels and the variables influencing them, as well as other issues concerning precisely quality, rational use and availability.

Moreover, a paragraph was introduced on the empirical analysis of data on the final prices of medicines in some developing countries. It is well known that the final price of a drug is a difficult variable to find, since, as it is not subject to any kind of regulation, it varies considerably from one pharmacy to another, even within the same country. Even if there were nationally fixed prices, they would most likely not be adhered to. Consequently, having reliable data would imply a thorough investigation in the field. Furthermore, to have additional information that can point to country-specific problems, it is necessary to collect data on mark-ups (taxes, retail margins, wholesale margin), the actual availability of drugs in the various facilities, the organisation of the national health system and the procurement mechanisms. Unfortunately, these data have not been collected systematically. However, as the debate on the role of prices in access to medicines has grown, consumer price surveys in sub-Saharan countries have multiplied in recent years; initially promoted by non-governmental associations independently, later the WHO also took an interest in the issue, and a database maintained by HAI (Health Action International) is currently being disseminated. Given the relevance of price analysis for the purposes of this thesis, it was decided to consider both the surveys conducted by HAI and MSF (Médecins Sans Frontières), as the information is complementary.

Within the discussion on the causes preventing access to medicines in sub-Saharan countries, the responsibilities of pharmaceutical companies have often been mentioned. They are accused of being only interested in making high profits, including through unfair market policies and without showing any commitment to their social role, i.e. health promotion. The pharmaceutical companies justify themselves by claiming, first of all, that they invest huge resources in research and that this, in a competitive environment where the state is absent, must be financed by the profits they make from sales, otherwise, without a continuous income, they will no longer be able to continue on the path of innovation and many needs will be left unsatisfied. In addition to justifying high prices, big pharma vigorously defends intellectual property rights, which prevent imitators from grabbing market share by copying someone else's invention. Given the role that the pharmaceutical industry plays in our societies, the fourth chapter presents a current overview of the pharmaceutical industry in Kenya and South Africa, highlighting the problems that caused much criticism in recent years.

The dimension of the problem

It is important to emphasise the magnitude of the problem of access to medicines in sub-Saharan countries, as the World Health Organisation estimates that it affects 1.3 to 2.1 billion people, equivalent to 30% of the world's population. The remaining 70%, excluding the 20% who live in industrialised countries, may still not have full access to the care they need at any point in their lives. In fact, the system is often inefficient and does not allow full access to this right, which is nevertheless part of the wider right to health, which is fundamental to any individual. Medicine is considered a primary good, because in certain pathological conditions it is the only solution that can save a person's life. The problem of access to medicines is part of the larger context of underdevelopment and deprivation that is characteristic of sub-Saharan countries.

Where the population lacks food and water resources, adequate school systems, the lack of health care infrastructure is a fact. Naturally, the situation is a self-perpetuating spiral: malnutrition makes the organism weak, which without defences can easily contract diseases, this prevents work and without income the patient cannot purchase treatment; the lack of water control leads to the contraction of infections, which in fact cause thousands of victims every day. In recent years, international bodies have proposed estimates of the costs that certain diseases, mainly HIV/AIDS and malaria, generate for the countries that are victims of these epidemics
Regardless of the economic impact, the social consequences on affected communities require urgent action.

Improving access to medicines may, however, be slower than improving the nutritional situation and the availability of water and schools, as it requires a more sustained effort, in investment in adequate health infrastructure and specialised medical staff, in public policies to defend the right to health. Without public support, many patients will never be able to pay for their medicines in full, even if they have goods for their subsistence. It is worth mentioning that the World Bank estimates that about half of the world's population has less than USD 2 per day, which makes it difficult not only to have access to essential medicines, but also to basic goods.

Despite the fact that the last few decades have witnessed an improvement in access to medicines in developing countries, many people remain deprived of the right to receive necessary treatment at a cost that does not involve debt or further deprivation. At this point, it seems legitimate to ask why this situation persists.

During the international debate on the obstacles to access to medicines, pharmaceutical companies are often mentioned because they have taken the lead in defending patent rights and, even using intellectual property protection, apply opportunistic market policies in an area, that of health, which would require the most desirable ethical spirit. This thesis deals extensively with the behaviour of pharmaceutical companies in the drug market in the Global South but tries to highlight the countless other problems in these countries. At the moment, the pharmaceutical companies appeal to these very problems to justify their actions: first and foremost, rampant corruption, the inefficiency of the distribution chain, and the absence of the state. Stressing that the responsibility does not lie solely with the pharmaceutical companies, who simply take advantage of the absence of regulations according to their own interests, it is considered appropriate to state that everyone should act responsibly in order to achieve an ambitious end result: universal access to medicines.

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