Access to Essential Medicine as Part of the Right to Health in Africa: Access to Essential Medicine Under International Human Rights Law, the Case of Kenya and South Africa

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Abstract

Access to health is a right under international human rights law. Since access to essential medicine is a core component of health, access to essential medicine should therefore be considered equally as a right. Essential medicine offers a cost-effective solution to many health problems in Africa; however, its access constitutes a major problem plaguing the continent. While many strategies have been unsuccessful over the years to solve this problem, African countries like Kenya and South Africa are increasingly applying a human rights-based approach in increasing access to essential medicine. This approach has increased access of essential medicine to the population, most of whom are poor, increased accountability of states toward their international obligations, and empowered the population to take action to assert this right against the state.

Keywords: International Human Rights, Health Law, Essential Medicine Access, Constitutional Right to Health, Positive Law, Kenya, South Africa, Uganda

I. Introduction

The World Health Organization first recognized the concept of a human right to health under international law when it declared, “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.” Since then the right has become enshrined in both conventional and customary international law, with Article 25 of the Universal Declaration of Human Rights recognizing the right to health as part of an

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adequate standard of living closely linked with other economic and social rights such as “food, clothing, housing and medical care and necessary social services.”\(^2\) The standard of the right to health in international law today is found in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which provides that States Parties recognize “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and that steps are to be taken by States in order to realize this right in the areas of (a) reduction of the still-birth rate and infant mortality; (b) improvement of environmental and industrial hygiene; (c) prevention, treatment and control of diseases; and (d) creation of conditions assuring to all medical service and attention in the event of sickness.\(^3\) Thus under international human rights law, the right to health consists of a set of social structures, norms, institutions, laws and an enabling environment that can better ensure that everyone enjoys this right.\(^4\)

Article 12 of the ICESCR defines the right to health as an inclusive right that extends to appropriate healthcare and other health determinants such as access to adequate sanitation, access to safe and portable water, adequate housing, and healthy environmental and occupational conditions.\(^5\) Access to essential medicine is a critical component of the right to health. While many countries have taken strategies over the years to solve the problem of access to essential medicine, the issue remains a major obstacle in Africa. Many African countries that have ratified international and regional treaties dealing with the right to health are seeking a human rights-based approach in making access to essential medicine an integral part of the right to health. Many African countries and organizations in a variety of contexts have used the right of access to medicines, but their use of the phrase in relation to human rights does not always imply the same meaning. Quite often, the phrase refers to treatment access for life-threatening diseases that affect critical public health needs, or


treatment access in cases of emergency, with a direct reference to these medicines.\footnote{6} In other instances, the phrase includes the category of neglected diseases, that is, diseases to which inadequate attention has been paid for research and development for appropriate treatments.\footnote{7} There has also been increasing reference to treatments for chronic diseases and conditions, such as pain management and cancer.\footnote{8}

Rights empower individuals and marginalized groups within any society to assert themselves against powerful entities in the public and private spheres and thereby draw attention to their plight.\footnote{9} Where the objects of rights include social goods or services, the rights further recast claims for access to such goods or services as moral and legal imperatives, rather than mere cries for help.\footnote{10} As such, rights affect the manner in which society views delivery of social goods and services and demand accountability from those responsible for this delivery.\footnote{11} A consequence of such rights is the impact it has on the systems and structures through which social, economic, and cultural goods and services are delivered, especially in situations where such rights are legally enforceable against architects and drivers of such systems and structures such as institutions.\footnote{12} Rights also simultaneously present substantive goals and outcomes towards which social delivery structures and systems must gear themselves, as well as yardsticks by which their achievement of these goals and outcomes is measured, and mechanisms through which non-achievement of the goals and


\footnote{9}{Marius Pieterse, \textit{Can Rights Cure? The Impact of Human Rights Litigation on South Africa’s Health System} (Pretoria, South Africa: Pretoria University Press).}


\footnote{12}{Ibid.}
outcomes is corrected.\textsuperscript{13} By doing this, rights have the power, over time, to significantly change the manner in which social delivery systems function.\textsuperscript{14}

Where rights are enforced through the court system, they alter the balance of power within the state and cause tensions between the courts and the legislative and executive branches of government over how, and from where, social delivery efforts are to be driven.\textsuperscript{15} A right to health is one of a range of socio-economic rights for which many states have accepted an obligation under international human rights law. However, in practice socio-economic rights are rarely given the same status as civil and political rights. While rights-based litigation in fields such as civil liberties are very common, health rights-based litigation are not very common globally, and is considered sometimes controversial. However, recent years have seen an increase in health rights-based litigation, especially access to essential medicine in a number of African countries, such as South Africa and Kenya. Whether or not this has or will lead to an increase in the enjoyment of health rights, the fact that governments are strengthening their public health policies to satisfy the health needs of its population in other African countries calls for an analysis of the place international human rights instruments play with respect to access to medicine. This article starts by briefly presenting some of the problems of access to medicine in Africa, and then argues that the right to health should include access to essential medicine. The article will proceed to show a link between health, human rights and access to essential medicine and will use international human rights law instruments to argue this position. The last part of the article will look at examples of countries like Kenya and South Africa. Given that these countries have legislated access to essential medication in their constitutions as a human rights, the article will look at how litigation has been used to claim this right, as well as the challenges these countries still

\textsuperscript{13} See S. Gruskin & D. Tarantola, “Health and Human Rights” in Perspectives on Health and Human Rights, eds. S. Gruskin et al. (2005), 33-43.


encounter in promoting access to essential medicine before proposing solutions.

II. Problems of Access to Essential Medicines in Africa

Essential medicine offers a cost-effective solution to many health problems in Africa, provided it is available, affordable and properly used. Essential medicine is defined as medicine that satisfies the priority healthcare needs of the population and are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. According to the World Health Organization (WHO) these medicines are selected on the basis of their estimated current and future health relevance, safety, evidence of efficacy, and comparative cost effectiveness. The United Nations Development Group defines access in this context as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.” Any medicine that satisfies these principles are published in the WHO’s model list of essential medicine, an inventory which is updated every two years and tailored towards regional or national health needs in a national Essential Medicines list (EML). Each country can use its national list as a tool to make priorities on their most pressing public health needs by focusing on public sector procurement and treatment of a limited high priority set of medicines. The situation regarding access to medicine has however changed because of recent advances in scientific and technological innovation, which has led to the development of new vaccines, reduced the

17 Ibid.
prevalence of infectious diseases such as polio and human papillomavirus,\textsuperscript{21} and decreased the global disease burden of HIV/AIDS. The invention of molecular targeted therapies has even showed early promise of treating cancer, and the biomedical industry has made strides in strengthening the prevention, treatment, and control of transmissible and non-transmissible diseases.\textsuperscript{22} Despite this scientific progress, millions of people on the African continent still face huge obstacles in accessing essential medicines.\textsuperscript{23}

The problems of access to essential medicine in Africa include:\textsuperscript{24}

1. The present research and development (R&D) model, which is largely market-driven, is ill equipped to address these problems.\textsuperscript{25} It is also ill prepared to respond to emerging infectious diseases such as Zika and Ebola, neglected tropical diseases (NTD) that predominantly affect populations in Africa.\textsuperscript{26} This has created an incoherence between innovation, which has been the driving force of R&D in creating new medicines, and the lack of access of such medicines in the African continent.

2. According to the drug industry, high costs stem from the fact that the development of drugs are lengthy, costly and risky, thus patent rights, which allow the inventors of new drugs to charge high prices, are necessary to provide incentives for R&D.\textsuperscript{27} The high cost of drug development thus constitute a huge obstacle to access to essential medicine.

3. There has also been a shift towards the production of certain drugs, which are more profitable in Western countries, while neglecting those that are needed in developing countries. In order to cope with large investments and reduce duplicate spending,
pharmaceutical companies have been involved in many mergers and industrial consolidation. It includes Glaxo and Wellcome, Sandoz and Ciba-Geigy, etc. These consolidations are mostly focused on the most profitable segments of the market, such as cardio-vascular conditions, cancer dermatology, neurology and infectious diseases, which are very common in developed countries, leaving tropical medicine largely out of their calculation but which constitute a large part of the essential medicine needed in Africa.\(^{28}\)

4. Counterfeit and substandard drugs also plague access to essential medicine in Africa. Patented drugs in some African countries are being copied where patent rights of pharmaceutical drugs are not adequately protected.

5. There is also the problems that arise because of differences in the notion of IP rights and cases of appropriation of the name and appearance of trademark drugs, especially in countries where the informal market plays a significant role.\(^{29}\)

6. In addition, most essential drugs required for the treatment of certain tropical diseases are progressively disappearing from the market because they are not commercially profitable. Most of these drugs, which were discovered in the 1950’s, are seldom or never used in developed nations. An example is the effort to treat epidemic bacterial meningitis, which is rampant in many African countries. Effective treatment of these bacteria involves chloramphenicol in oily suspension, which is comparable to the traditional treatment using ampicillin.\(^{30}\) The lower cost of chloramphenicol in oil suspension-only is one-tenth of the cost of ampicillin and its simple administration makes it particularly suitable to the difficult working conditions in some African countries, especially during epidemics. This was the case in Nigeria in 1996 when over 100,000 cases were seen.\(^{31}\) Despite this epidemic the availability and production of chloramphenicol in oily suspension is no more guaranteed because Roussel-Uclaf laboratory stopped its production in 1995 and transferred it to another laboratory whose production is not adequate to respond to such large-scale epidemics. This is the case with many other serious tropical diseases in Africa.\(^{32}\)

7. In addition, many essential drugs are not adapted to field conditions. Tuberculosis caused the death of three million people in 1997, but currently the treatment regime known as


Directly Observed therapy, short-course (DOTS) is impractical and compliance is not very effective as only 23% of the world’s population have access to the WHO tuberculosis control strategy.\textsuperscript{33}

Faced with these problems, there is a need to develop a new approach to solve the issue of lack of access to essential medicine in Africa. This article takes the position that access to essential medicines in Africa should be solved through a human rights-based approach. The UN recognizes the right to health as a human right. If access to medicine, which is an integral part of the right to health, is treated as a human rights issue, there are high chances that national governments and the private sector will consecrate more energy, resources and time to develop strategies and ways to come up with the appropriate solutions to increase access to essential medicine. One of such ways is by explicitly making the right to health a positive right in the constitution.

III. The Right to Health Should Include Access to Essential Medicine

In Human Rights Obligations of Non-State Actors, Andrew Clapham writes, “Perhaps the most obvious threat to human rights has come from the inability of people to achieve access to inexpensive medicine, particularly in the context of HIV and AIDS.”\textsuperscript{34} This statement was made in reference to obstacles and threats to human rights from Trade-Related Aspects of Intellectual Property Rights (TRIPS), which many will argue operates in ways that are incompatible with the very notion of human rights. The right to health, in the interpretation of the Committee on Economic Social and Cultural Rights (CESCR), means that “States Parties … have a duty to prevent unreasonably high costs for access to essential medicines.”\textsuperscript{35} Thus the human right to essential medicines is a derivative right within the

\textsuperscript{33} J. Crofton, P. Chaulet, D. Maher, Principes pour la prise en charge de la tuberculose à bacilles résistants (Geneva: World Health Organization, 2000).

\textsuperscript{34} Andrew Clapham, Human Rights Obligation of Non-State Actors (Oxford: Oxford University Press, 2006), 175.

\textsuperscript{35} Committee on ICESCR, “The Right of Everyone to Benefit from the Protection of the Moral and Material interests Resulting from any Scientific, Literary or Artistic Production of which He or She is the Author,” Art 15, paragraph 1(c), General Comment No. 17 (2005), UN doc. E/C.12/GC/1, January 12, 2006, para. 35.
broader right to the highest attainable standard of physical and mental health as espoused in the preamble of the World Health Organization (WHO). As a component of the right to health, the right to essential medicines depends not only on the production, distribution, and pricing of medicines, but also on the incentives for research and development of drugs needed to treat diseases in Africa.

1. The Link between Health and Human Rights

There are complex linkages between health and human rights, as violations or acts against human rights such as torture, slavery, violence against women and children and harmful traditional practices can have serious health consequence. Thus, health policies and programs can promote or violate human rights such as the right to participation, right to information and right to privacy in the ways they are structured. In addition, vulnerability and the impact of ill health can be reduced by taking steps to respect, protect and fulfil human rights obligations such as right to health, education, food and nutrition, and freedom from discrimination. The exercise of governmental functions in healthcare forms the centerpiece of the development of a human rights approach to health. The remnants of the Ancient Roman sewage system are eloquent testimony to the fact that government has striven to improve sanitation and thus public health since ancient times. In addition, German monarchs in the 18th century regarded the protection of public health as part of their duty to build, a gute policey, a good order. The concept of human rights to health, however had not developed until after WWII, when the WHO was created in 1948. The preamble of the WHO became the first international legal document to contain an explicit right to health by proclaiming, “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief,

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39 Ibid.

economic or social condition.” The preamble goes further in defining health as “A state of complete physical, mental, and social wellbeing and not merely the absence of diseases and infirmity.”

This definition became very influential and was taken up by numerous legal instruments such as article 25 of the Universal Declaration of Human Rights (UDHR). Article 12 of the ICESCR, the Convention on the Elimination of all forms of Racial Discrimination, Convention for the Elimination of forms of Discrimination against Women (CEDAW), Convention on the Rights of the Child (CRD), African Charter on Human and Peoples Rights, the General comments on the Rights to Health, Alma Alta Declaration and many others. Thus instead of treating it as a right to be healthy, the WHO actually proclaims health as an equal right, which should be shared and enjoyed by everyone. As such, the right to health implicates the promotion, protection and health care provision. The right to the highest attainable standard of health in international human rights law is a claim to a set of social arrangements, norms, institutions, laws and enabling environment that can best secure the enjoyment of these rights. The most authoritative interpretation of the right to health is articulated in article 12 of the ICESCR. The committee on ESCR, which monitors the ICESCR, adopted the General comment No 14 on the right to health, which serves to clarify the nature and content of individual rights and state party’s obligations.

Paragraphs 34-37 of General Comment No. 14 clearly describe governments’ legal obligations to respect, protect, and fulfill the right to health. The duty to respect is a negative obligation to refrain from interfering with the enjoyment of health rights. The duties to protect and to fulfill impose positive obligations on states to take measures to safeguard (to protect) and to take measures

42 Ibid.
44 See Gruskin & Tarantola, “Health and Human Rights.”
46 Ibid.
to ensure that health rights are enjoyed.\textsuperscript{47}

The General Comments No. 14 also recognized that the right to health is closely related to and dependent upon the realization of other human rights, including the right to food, housing, education and many others. The general comments set out four criteria by which to evaluate the right to health: availability, accessibility, acceptability, and quality, commonly known as AAAQ.\textsuperscript{48}

1. \textit{Availability}: functioning public health and health-care facilities, goods and services as well as programs have to be available.
2. \textit{Accessibility}: health facilities, goods and services need to be accessible to everyone without discrimination within the jurisdiction of the state party. Accessibility have four overlapping dimensions, (a) Non-Discrimination, (b) Physical accessibility, (c) Economic accessibility or affordability (d) Information accessibility.
3. \textit{Acceptability}: all health facilities, goods and services must be respectful of medical ethics and culturally appropriate, sensitive to gender and life cycle requirements as well as designed to respect confidentiality and improve health status of those concerned.
4. \textit{Quality}: Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

Thus, AAAQ helps to identify the specific legal obligations of states to realize the right to health.\textsuperscript{49}

\section*{2. Access to Essential Medicine is a Human Right}

The United Nations (UN) has recognized the importance of access to essential medicines by making it a Millennium Development Goal target.\textsuperscript{50} Despite this recognition by the UN, the lack of access to essential medicines remains ubiquitous in many parts of the world. A general overview of the international human rights framework relating to access to medicine shows that it is embedded in the right to the highest attainable standard of health. In general comment 14 (2000) on the right to health, the committee on Economic, Social, and Cultural

\textsuperscript{47} Oehlke et al., “Access to Medicines and Human Rights.”


\textsuperscript{49} Ibid.

\textsuperscript{50} MDG Gap Task Force, \textit{Delivering on the Global Partnership for Achieving the Millennium Development Goals}. 
rights (UNCESCR) interprets the normative content of Art 12 of the ICESCR. The committee explained that the right to health should be understood as encompassing a package of interrelated and mutually supporting rights that operate jointly to enable the achievement of the highest attainable standard of physical and mental health. This package comprises health-related freedoms – such as rights of control over health and body, personal autonomy in the seeking of health care, input in health-related decision making, reproductive freedom, and freedom from torture, non-consensual medical treatment and medical experimentation. However, it also comprises of health-related entitlements that afford citizens “the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health. It also consists of the right to a system of health protection, which provides equality of opportunity for people to enjoy the highest attainable standard of health.”

The UNCESCR further states that compliance with the right should be assessed with reference to the Availability, Accessibility, Acceptability and Quality of health care facilities, goods, and services. However, the convention recognizes that realizing the right to health including its constituent element is very challenging and thus may be realized progressively. Under the principle of progressive realization, “State parties have a specific and continuing obligation to move as expeditiously and efficiently as possible towards the full realization of the right to health and other related human rights of older people.” Thus although the ICESCR requires the progressive realization of the right to health in the context of limited resources, there is a core set of minimum obligations which are not subject to progressive retaliation, including access to essential medicines.

While states generally hold the core responsibility for the provision of medicine, this responsibility is also shared with other non-state actors such as pharmaceutical companies.

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52 Ibid., “The Right to the Highest Attainable Standard of Health,” paras 1, 3-4, 7-9.
53 Ibid.
54 CESCR, General Comment No. 14.
The former UN special rapporteur on the right to health held that pharmaceutical companies have a human rights responsibility, such as the duty to take all reasonable measures to make new medicines as available as possible for those in need.\footnote{56} In addition, the UN Human Rights Council in 2011 unanimously endorsed the building principles on business human rights which obliges the private sector to take responsibility for violations of human rights related to access to medicine.\footnote{57} More so, the international community has human rights obligations to assist governments that lack the resources to achieve their minimum core duties through international cooperation and assistance.\footnote{58} Also in a situation of disaster, the international community bears the duty to contribute to relief and humanitarian assistance by providing medical supplies as a matter of priority.\footnote{59}

The contribution of a human rights based approach (HRBA) to access to medicines, is that it identifies all human beings as having an interdependent, indivisible, non-discriminatory, participatory and interrelated rights to health and access to medicine. In addition to entitlements and duties and as firmly stated by the CESCR\footnote{60} and the WHO,\footnote{61} the HRBA also applied its fundamental principles of universality and inalienability, indivisibility, interdependence and interrelatedness, equality and non-discrimination, participation and inclusion, accountability and the rule of law to universal access policies to essential medicine.\footnote{62} In addition, the HRBA to access to essential medicine pay particular attention to the disadvantaged, less privileged, marginalized, and neglected members of society and

\footnotesize{\begin{itemize}
\item \footnote{58} Article 2(1) of the ICESCR calls upon all states, individually “and through international assistance and cooperation,” to guarantee the progressive realization of human rights.
\item \footnote{59} CESCR, \textit{General Comment No. 14}, para. 40.
\item \footnote{60} CESCR, \textit{General Comment No. 14}.
\item \footnote{61} Xavier Seuba, “Round Table: A Human Rights Approach to the WHO Model List of Essential Medicines,” \textit{Bulletin of the World Health Organization} 84.
\end{itemize}}
empowers the entire population with the ability to achieve outcomes through an inclusive, transparent and responsive process.  

The public health flexibilities available under TRIPS, regarding pharmaceutical products for example, include compulsory licensing, parallel importation, and discretion in defining domestic standards of patentability. On the other hand, the pharmaceutical companies bear the responsibility to respect human rights vis-à-vis the Ruggie trinity to protect, respect, and remedy. Within this framework; corporations have a duty to: (a) avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur; and (b) prevent or mitigate adverse human rights impacts that are directly linked to their operations, products, or services by their business relationships, even if they have not contributed to those impacts. Thus, pharmaceutical firms bear an utmost responsibility to act with care and due diligence to avoid violating the right to health enshrined in international human rights instruments. These responsibilities become obvious when pharmaceutical companies start to prioritize the enforcement of their IP rights at the expense of their obligations for respect the rights to health.


International human rights law is clear about the human rights duties imposed on states in relation to essential medicines and their implications for other legal duties. Article 12 of the ICESCR that grants the right to health has been interpreted by the United Nations CESCR to place priority on states regarding access to essential medicines. In General Comment 14 on the Right to the Highest Attainable Standard of Physical and Mental Health, the Committee stresses the importance of state duties towards essential medicines in a number of domains, writing:

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64 See the UN Sub-Commission on the Promotion and Protection of Human Rights, the UN Global Compact, and the Organization for Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises.

65 States have a duty to protect human rights, corporations have a duty to respect human rights, and states must ensure that there is access to effective remedy when abuses occur within their territory and/or jurisdiction.


67 CESCR, *General Comment No. 14*. 
1. The Committee indicates that the essential elements of the right to health include ensuring sufficient availability of functioning “public health and health-care facilities, goods and services” including “essential drugs, as defined by the WHO Action Program on Essential Drugs.”

2. The Committee locates essential medicines within core obligations under the right to health. In General Comment 14, the Committee indicates that core obligations under the right to health include providing “essential drugs, as from time to time defined under the WHO Action Program on Essential Drugs.”

The Committee is explicit about the significance of a core obligation. While all other duties under the ICESCR are subject to progressive realization within maximum available resources, “a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out, which are non-derogable.” Whatever the strength of these duties, the implication holds that a state’s core obligations have a temporal and substantive priority over other human rights duties and over duties under other legal regimes. Although General Comment 14 refuses to specify the exact health facilities, goods and services that must be delivered by states, partially because of differing health needs among populations and partially because of differing levels of development, there is a basic core obligation to guarantee access to essential medicines. As per General Comment 14, realizing the right of access to essential medicine is contingent upon the realization of four interrelated elements of human rights. Medicine must be:

(1) Of good quality,
(2) Accessible, including affordability, physical accessibility, and accessibility of information,
(3) Acceptable and
(4) Available

In tandem with these interrelated elements, the WHO has outlined the following four key building blocks as essential toward ensuring access to essential medicines in national health systems. They include:

1. Rational selection and use of essential medicines based on national lists of essential medicines and treatment guidelines;

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68 Ibid.
69 Ibid.
70 Ibid.
71 Grabowski, “The Effect of Pharmoeconomics.”
2. Affordable prices for governments, health care providers and individuals;
3. Fair and sustainable financing of essential medicines as part of the national health care system through adequate funding levels and equitable prepayments systems, to ensure that the poor are not disproportionately affected by medicine; and
4. Reliable health supply systems to ensure sufficient and locally appropriate combination of public and private service providers.72

The ICESCR in its Art 2(1) calls for the progressive realization of the economic and social rights, which in reality means that it recognizes that many countries, especially in Africa, have problems relating to resource constraints, thereby allowing these countries to progressively realize their obligations over time. This can be taken to mean that, theoretically, the lack of resources can be used as grounds for non-compliance by a state. However as explained above and supported by the Limburg Principles on the Implementation of the ICESCR, “the progressive realization of rights also suggests that states, regardless of their level of economic development, are obliged to take measures immediately and move as expeditiously as possible towards the realization of those rights.”73 This implies that states must, within the context of access to essential medicine, create and put in place a reasonable action plan to improve access to essential medicine on a continuous basis.74 The obligation of states to provide essential medicine to its population should also be recognized in national and domestic laws and given appropriate priority for public financing by way of adequate allocation of budgets. Thus, laws and policies within national health systems such as universal health coverage, medicine pricing, and the broader legal order such as IP protection and trade should be aligned in achieving universal access to essential medicine.75 This may involve the government making full use of the trade options under TRIPS flexibilities to safeguard access to essential medicine.

Regional instruments and documents agreed upon by the health community also clearly recognize the right to health, such as The African Charter on Human and Peoples’ Rights (art. 16), which provides that: every individual shall have the right to enjoy the best attainable


74 Oehlke et al., “Access to Medicines and Human Rights.”

75 Ibid.
state of physical and mental health, and State Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.\textsuperscript{76}

In addition, the 1978 Declaration of Alma-Ata establishes a clear and important link between the provision of primary health care and the provision of essential drugs.\textsuperscript{77} All of these instruments consider health as fundamental human rights, and can be used to support access to medicines claims in domestic courts. International law gives clear guidance to states, and their implementation should be monitored in practice. Almost all countries in Africa have ratified the ICESCR and many have recognized and included a degree of protection of the rights to public health in their national laws, including Kenya and South Africa, which have included the right of access to medicine in their constitution.

Apart from the responsibilities of states, non-state actors such as pharmaceutical companies have human rights responsibilities with respect to access to essential medicine. Paul Hunt, UN Special Rapporteur on the rights to health, has explained that pharmaceutical companies have a duty to take all reasonable steps to make a medicine as accessible as possible after it has been marketed, including to those who cannot afford them because of high prices, and that these steps should be taken within a viable business model. He stresses further that a company may be in breach of its responsibilities under the right to health if a patent is granted without these steps taken.\textsuperscript{78} This applies squarely to Africa, given that most of the countries lack the financial resources to fulfill the right of access to essential medicine to their citizens because of the high cost of drugs. It is thus incumbent on pharmaceutical companies to respect their human rights obligations and act as partners to fulfill the human rights of access to medicine.

### IV. Human rights-based Link between Right to Health and Access to

\textsuperscript{76} The African Charter on Human and Peoples' Rights (art. 16), http://www.achpr.org/instruments/achpr/#a16 .

\textsuperscript{77} WHO, Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, September 6-12, 1978.

Medicine in Kenya and South Africa

The Human Rights Based Approach (HRBA) is a framework that can be used and applied in litigation, advocacy and programming in the relationship between states and citizens. It is shaped by international human rights law, and it specifically calls for human rights to guide every relationship between rights holders (which include individuals and groups with rights) and duty bearers (who are actors) with an obligation to fulfill those rights such as states and non-state actors. Additionally the HRBA is also intended to strengthen the capacities of rights holders to claim their entitlements and to enable duty bearers to meet their obligations as defined by international human rights law. It does so by drawing attention to marginalized, excluded populations, and the disadvantaged, ensuring that they are treated both as rights holders and duty bearers with the ability to participate in the outcome of processes. The case of Kenya and South Africa, just like other African countries, shows that each time a HRBA is used to solve health problems, it leads to the satisfaction of the majority of the population, especially the most vulnerable, with respect to access to essential medicine. The claims of individuals or groups have been particularly efficacious when access to medicines is linked to a country’s constitutional right to health or human rights treaties ratified by the government. For example, a study identified that state recognition of the right to health in international or domestic law created a supportive environment for cases in which access to essential medicines was claimed as a derivative of the right to health and thereby reinforcing the enforceability through domestic courts. The starting point for any human rights discourse at the international level is the Universal Declaration of Human Rights (UDHR). In this regard, the first authority and guide on human rights is the UDHR, whose status has grown to universal acceptance. It is also widely believed that the whole UDHR or some of its provisions have attained customary law status. Therefore, the authoritative first reference to the right to health remains article 25(1) of the UDHR. It

80 Ibid.
provides as follows: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”

By virtue of being members of the United Nations (UN), Kenya and South Africa subscribe fully to the ideals and provisions of the UDHR, including its commitment to the right to health. Apart from the UDHR, both Kenya and South Africa are jointly and separately members of other legally binding international human rights treaties also codifying, in their texts, the right to health. Most prominently of these treaties and their provisions include: article 12 of the ICESCR, article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and article 24 of the Convention on the Rights of the Child. As far as regional organizations are concerned both Kenya and South Africa have extensive obligations concerning the right to health at the international level, and the same position is also true at the regional level. These are some of the treaty provisions that codify the right to health at the regional level: Art. 16 of the African Charter on Human and Peoples’ Rights (African Charter); Art.14 of the Protocol to the African Charter on the Rights of the Women; and Art.14 of the Protocol to the African Charter on the Rights of the Child. These treaties create more obligations for Kenya and South Africa under international Law.

As far as national laws are concerned, the Kenyan and South African constitutions are unique mainly because they include, amongst many other innovations, justiciable socio-

83 Ibid.
economic rights including the right to health.\textsuperscript{89} In this regard, in 2002, the South African Constitutional Court in the \textit{Minister for Health and Others v Treatment Action Campaign and others} (popularly known as the TAC case) was capacitated to uphold that the right to health encompasses access to essential medicines for everyone. In this particular case, the anti-retroviral drug, Nevirapine, was found to be an essential medicine in as far as it prevented mother-to-child-transmission (MTCT) during pregnancies. Accordingly, the failure by the South African government to make Nevirapine accessible to all pregnant women in South Africa was found to be a violation of the right to health as enshrined under the South African Constitution Section 27. Similarly, in 2012, almost a decade after the TAC case, the Kenyan High Court in the \textit{P.A.O and Others v Attorney General} (popularly known as the Patricia Asero case) also declared as unconstitutional certain provisions, specifically, sections 2, 32 and 34 of the Kenya Anti-Counterfeit Act (ACA). In reaching its verdict, the High Court took the view that the ACA was unconstitutional because it infringed on the constitutional rights to health, life and dignity of the three petitioners living positively with HIV and AIDS in Kenya.

From a textual analysis of the relevant right to health provisions of both countries, firstly, South Africa recognizes the right to “have access to health care services,” while Kenya recognizes the right to the “highest attainable standard of health, which includes the right to health care services.”\textsuperscript{90} Arguably, therefore, Kenya appears to have a slightly broader scope of the right to health than South Africa. Additionally, South Africa imposes an obligation on the government to take reasonable measures while the Kenyan Constitution specifically implores on the Kenyan government to take legislative, policy and other measures, including setting of standards to realize the right to health. Kenya’s Constitution therefore appears to have a greater degree of specificity than the South African Constitution, which may be more beneficial for the protection of the right to health in the country, and potentially useful as a model for other African countries grappling with this question.

\textbf{A. Right to Access to Medicine in Kenya: The Anti-Counterfeit Case}

This case is particularly interesting because the new Kenyan Constitution came into

\textsuperscript{89} See Article 43(a) and Section 27 of the Kenyan 2010 Constitution and the 1996 South African Constitution respectively.

\textsuperscript{90} Ibid.
force in 2010, after the case had been filed, and specifically provided for the right to health for all of Kenya’s citizens, as well as giving direct effect to all international laws ratified by the Kenyan government. The case is also an example of effective human rights-based work in advancing access to medicines in Kenya. In 2008 Kenya passed the Anti-Counterfeit Act aimed at fighting counterfeit goods and illegal importation of drugs of substandard quality. However, despite the good intention of the Kenyan government, the law posed a threat for people living with HIV/AIDS in their pursuit of essential and life-saving medicines because it failed to make a distinction between counterfeit goods and generic medicine. By failing to distinguish between counterfeit goods and generic medicines, the Act threatened to limit the availability and affordability of Anti-Retroviral Drugs (ARVs) in Kenya. Thus because 90% of Kenyan patients with HIV depend on generic drugs imported by the government and donors, the Act’s potential repercussions could have been tremendous. On the whole, the incidence of HIV in Kenya is especially high, particularly for women and children. In 2009, the law firm of Majanja Luseno & Company Advocates filed a case on behalf of three adults—Patricia Asero, Maurine Murenga, and Joseph Munyi, three people all living with HIV/AIDS—bringing on a constitutional challenge to the High Court of Kenya. The plaintiffs had been taking HIV drugs for the last ten years since the generic ARV HIV drugs became more and widely available because of the 2001 Industrial Property Act (IPA).

The IPA is defined as “an Act of Parliament to provide for the promotion of inventive and innovative activities, to facilitate the acquisition of technology through the granting and regulation of patents, utility models, technovations and industrial designs, to provide for the establishment, powers and functions of the Kenya Industrial Property Institute and for purposes incidental thereto and connected therewith.”

The cost of treatment with non-generic ARVs is very expensive for an average Kenyan to afford. The IPA was crucial in making such essential medicines available to large number of Kenyans because it allowed for parallel importation, which enables the importation of non-


93 CESC, General Comment No. 14.

counterfeit drugs from other countries without the permission of the intellectual property owners.\textsuperscript{95} Parallel importation can result in the availability of much cheaper pharmaceuticals in the local market. Under Section 58(2) of the IPA as read with rule 37 of the Industrial Property Regulations 2002, it authorizes the importation of a generic version of an on-patent drug (e.g., importation of generic lamivudine manufactured by Cipla without the authorization of GlaxoSmithKline). This all changed in 2008, when Kenya’s Parliament passed the Anti-Counterfeit Act (Act No. 13 of 2008).\textsuperscript{96} This Act included essential medicines in the definition of “counterfeit” goods, making it an offense to sell or purchase such medicines, and allowing the intellectual property owner to ask the commissioner to seize and detain all suspected counterfeit goods. This presented a significant threat to parallel importation, and therefore to the availability of cheaper ARVs. However, the plaintiffs had to adhere strictly to their treatment program, taking three tablets a day; failing which the medication risked becoming drug-resistant, which would then necessitate changing to a more expensive drug.

The three applicants argued that the Act would affect their ability to access affordable and essential medicines, including generic medicines. This, they argued, would infringe on their rights to life, dignity, and the highest attainable standard of health as outlined in Articles 26(1), 28, and 43(1) a of the 2010 Constitution of Kenya.\textsuperscript{97} The initial petition was filed in 2009, before the new Constitution came into force, and therefore the prayers for relief were much more limited. Under the old Constitution, people living with HIV had to link access to treatment and the right to health with the right to life, given the absence of an express provision on the right to health.\textsuperscript{98} Before August 2010, Kenya was a dualist state, whereby a treaty did not become law even after ratification nor would the courts apply it, until and unless parliament passed an independent law importing the provisions of that treaty. Since


August 2010, Article 2(6) of the Constitution makes any ratified treaty or convention part of Kenyan law insofar as it does not contravene any provision of the constitution. Thus, once the government ratifies any treaty, it is law and courts can apply it without the need for legislation importing its provisions; this makes all internationally ratified treaty into law, including international human rights treaties dealing with health.

AIDS Law Project Kenya (ALP), an NGO, and the United Nations Special Rapporteur for Health, Anand Grover, were enjoined as interested parties to this case. Arguing that the Act amounted to a violation of their rights to life, dignity, and health, applicants urged the government to consider the Act again and re-draft it as it related to the definition of counterfeit medicine. More specifically, the petitioners claimed that the Act, as written in section 2, failed to exempt generic medicines from its definition of “counterfeit goods,” which was referred to as: “manufacture, production…or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods.” Thus by neglecting to outline a clear distinction between both terms, the Act had the potential to prohibit the importation and manufacture of generic medicines in Kenya. The Act also outweighed the positive effects of the Industrial Property Act (2001) which had allowed for parallel importation of medicines put legitimately on the market elsewhere, making generic drugs affordable and available in Kenya.

Later enjoined as an interested party, the United Nations Special Rapporteur for Health, Anand Grover, underscored that “legitimately produced” generic medicines had been conflated with goods that violate private intellectual rights. He emphasized that this conflation was “likely to have a serious adverse impact on the availability, affordability and accessibility of low-cost, high-quality medicines.” Grover envisaged a variety of scenarios including that medicines, deemed safe and effective by regulatory mechanisms, might be withheld at Kenyan checkpoints. He also predicted significant delays on imported generics and a drastic rise in the price of ARVs.

In 2012, three years after the Anti-Counterfeit Case was filed, the High Court of Kenya ruled that the 2008 Anti-Counterfeit Act violated the rights to life, human dignity, and

99 Anti-Counterfeit Act.

100 Alice Diver and Jacinta Miller, Justiciability of Human Rights Law in Domestic Jurisdictions (Switzerland: Springer International Publishing, 2016).
health as protected by the Constitution of Kenya. Justice Mumbi’s ruling affirmed that the provisions within the Act, particularly sections 2, 32, and 34, had construed counterfeit products with generics, and had impinged upon Kenyan patients’ access to affordable and essential drugs and medicines, thereby infringing upon their fundamental rights to life, human dignity and health as protected by the Constitution of Kenya and in international instruments ratified in line with Article 2(6) of the Constitution. The verdict in this case reaffirmed the rights of Kenyan patients living with HIV/AIDS and the obligation of the Kenyan government to fulfill its positive obligations towards them. In her ruling, Judge Mumbi stated, “There can be no room for ambiguity where the right to health and life of the petitioners and the many other Kenyans who are affected by HIV/AIDS are at stake.”

This case resulted in the suspension of significant portions of the Anti-Counterfeit Act, in particular relating to parallel importation. The Court referenced paragraph 35 of General Comment No. 17 of the CESCR, stating that “[s]tates parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights.” The case also emphasized the importance of the right of the petitioners to access essential medicine over the protection of enforcing intellectual property rights. In addition, it also reaffirms as well as stresses the fact that the protection of consumers should not be collateral in advancing the protection of Intellectual Property. This case has been hailed as a milestone in affirming the right to access to medicine under international law.

B. Right to Access Essential Medicine in South Africa

The extent to which rights can be used as political tools to effect structural change is obviously partially dependent upon the manner in which they are phrased in legal instruments. In South Africa, the content, outcomes and implementation of the legislative and policy processes set by the right to health finds expression in the 1996 South African

101 Ibid.
102 Ibid.
103 Ibid.
104 Oehlke et al., “Access to Medicines and Human Rights.”
Constitution.\textsuperscript{105} South Africa has acceded to some, though not all, of the international treaties dealing with the right to health. However, beyond specific treaty obligations, the understanding of the right to health at international law must influence the manner in which the right and its accompanying obligations are understood in the context of the Constitution.

According to section 39(1) of the Constitution, courts must promote the underlying values of an open and democratic society and must consider international law. Section 233 further determines that when interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law. These sections thus aims to align the understanding of the ambit and scope of relevant South African constitutional provisions to corresponding elements of the “health rights package” in international law.\textsuperscript{106}

South Africa has accepted the justiciability of the right to health as a necessity for advancing the right to health, including access to essential medicines.\textsuperscript{107} Generally, justiciability of the right to health under the South African Constitution means that courts have a say in the manner in which the right to health is understood and implemented. Although the linchpin of transforming the right to health embodied in the Constitution into reality is the duty of the legislature and executive, courts have been constitutionally empowered to oversee the state’s compliance with the right to health.\textsuperscript{108} According to section 38 of the Constitution, anyone may approach a court for appropriate relief, either in their own interest, the interests of another or the public interest when a right in the Bill of Rights has been infringed or threatened.\textsuperscript{109} This section makes the right to health justiciable so that a judge can consider this right in a concrete set of circumstances, a position that has been affirmed by the Constitutional Court of South Africa (CCSA), which proclaimed that the

\begin{itemize}
\item \textsuperscript{105} Pieterse, “Can Rights Cure?”
\item \textsuperscript{106} Economic and Social Council, \textit{Constitution Adopted by the United States of America and Other Governments respecting a World Health Organization}.
\item \textsuperscript{108} Christopher Mbazira: \textit{Ligating socio: economic rights in South Africa, a choice between corrective and distributive justice} (Pretoria: Pretoria University Law Press, 2009).
\item \textsuperscript{109} Grabowski, “The Effect of Pharmoeconomics.”
\end{itemize}
right to health is judicially enforceable. Thus a justiciable right to health is an important step in rectifying the problem of access to essential medicines in South Africa. The adoption of a positive legal entitlement to health for all citizens means that the courts are empowered to enforce the right to health during adjudication. For victims of a violation of the right to health and access to essential medicine, it is important that a judicial or quasi-judicial human rights body can adjudicate their complaints in this regard, as it contributes to the protection and realization of the right to access to essential medicine and further determines the meaning of this right.

Minister of Health v Treatment Action Campaign (TAC)

The case emanated from public discontent with the scarcity of antiretroviral drugs called nevirapine at some government hospitals. The scarcity of the antiretroviral drugs was attributed to a narrow government program for the prevention of mother-to-child transmission of HIV (PMCT). The program had been devised and implemented by the Minister of Health, in consultation with provincial health authorities on behalf of the central government. It entailed administering a single oral dose of the drug to the mother and a single oral dose to the baby at the time of birth. The program was not universal, but restricted by government to 18 pilot sites. Furthermore, doctors working at public health facilities outside the 18 sites were banned from prescribing nevirapine. The restrictions did not, however, apply to the private health sector. The consequence of the ban was that only 10% of babies born at public health facilities and their mothers had access to nevirapine.

The government did not state when the program would be widened to cover all of the public health sector. The South African government gave two main reasons why it was limiting the nevirapine program. One of the reasons was to do with its concerns about the health impact of nevirapine despite the fact that nevirapine had been successfully registered as a

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113 Ibid.
safe medication while the other intention is linked to the need to study the feasibility and cost of providing a comprehensive package for PMCT to all the public health facilities.\textsuperscript{114} In this regard, the pilot sites would serve as centers for ascertaining the capacity of the government to provide on a universal basis not only nevirapine, but also attendant services and supplementary therapy, including the following: voluntary HIV and AIDS testing and counselling services, follow-up services, formula milk where bottle-feeding was substituted for breast-feeding, antibiotics, and vitamin supplements. The data gathered from the pilot sites would assist the government in developing a universal comprehensive health program.\textsuperscript{115} The decision by government to restrict the program to the pilot sites was challenged in the High Court by a number of applicants of which the TAC were the principal applicants. The applicants’ argument was that the restrictions on the nevirapine program constituted a number of breaches of the Constitution, including the right to health provided under section 27 (92) of the Constitution.

The High Court proceeded on the basis that section 27 was determinative of the issues and ruled in favor of the applicants. the court held that government had breached sections 27(1) and 27(2) in that it acted unreasonably (a) in refusing to make nevirapine available in the public health sector, where the attending doctor had considered it medically indicated, and (b) in not setting a timeframe for a universal program for PMCT.\textsuperscript{116} On appeal, CCSA interpreted the state's obligations in terms of section 27 of the Constitution in light of the international obligations that provides the right to health to ensure access to essential medicines. The CCSA maintained that the available medical evidence showed that the drug could be administered without any known harm to the mother or child. Any side effects of the drug were greatly outweighed by the expected benefits. In essence, the CCSA ordered the government without delay to (a) Remove the restrictions that prevented nevirapine from being made available for the purpose of PMCT at public health facilities outside the pilot sites (b) Permit, facilitate and expedite the use of nevirapine for PMCT at state expenses. This verdict was hailed as the judgment that saved millions and reaffirm the impact of international human rights law relating to the access to essential medicines when enshrined

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\begin{footnote}{115}{Hunt and Khosla, “Are Drug Companies.”}
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\begin{footnote}{116}{Grabowski, “The Effect of Pharmoeconomics.”}
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into national laws. From analysis of the above cases, it is possible to protect access to essential medicines under the right to health framework.

V. Challenges in the Realization of the Right to Access to Essential Medicine

The increasing visibility and prominence of the right to health in international human rights law has been a special feature in recent decades. It has been taken up by members of civil society, academics, health professionals, lawyers and courts in several jurisdictions as a tool to address health inequalities at the local and international level, in issues relating to access to essential medicines. But it has equally been the subject of derision and scorn by human rights skeptics who have described it as lacking foundation, nebulous, and incapable of implementation. The international community has recognized the reality that, due to the great extent of the prevailing socio-economic need as well as the significant resource implications of realizing socio-economic rights, States cannot immediately be expected to comply with all of the obligations imposed on them by the said socio-economic rights.117 For this reason the ICESCR, as well as several other international and regional human rights instruments, affirms that there are limits to the extent to which socioeconomic rights may be enforced at any given time. Article 2(1) of the Covenant determines that states must take deliberate steps, to the maximum of their available resources, in order to achieve progressively the full enjoyment of all socio-economic rights. This article has been criticized for introducing a progressive retaliation of the rights by states but failed to provide sufficiently concrete standards against which to measure compliance by states with their obligations, thereby perpetuating the perception that socio-economic rights amount to unachievable ideals rather than enforceable rights.118 An explanation to this gap has been made by the bold and innovative General comment 3 of the CESCR. The CESCR, in General Comment 3;

“The principal obligation of result reflected in article 2 (1) is to take steps “with a view to achieving progressively the full realization of the rights recognized” in the Covenant.


118 Ibid.
The term “progressive realization” is often used to describe the intent of this phrase. The concept of progressive realization constitutes a recognition of the fact that full realization of all economic, social and cultural rights will generally not be able to be achieved in a short period of time. In this sense the obligation differs significantly from that contained in article 2 of the International Covenant on Civil and Political Rights which embodies an immediate obligation to respect and ensure all of the relevant rights. Nevertheless, the fact that realization over time, or in other words progressively, is foreseen under the Covenant should not be misinterpreted as depriving the obligation of all meaningful content. It is on the one hand a necessary flexibility device, reflecting the realities of the real world and the difficulties involved for any country in ensuring full realization of economic, social and cultural rights. On the other hand, the phrase must be read in the light of the overall objective, indeed the raison d’être, of the Covenant, which is to establish clear obligations for States parties in respect of the full realization of the rights in question. It thus imposes an obligation to move as expeditiously and effectively as possible towards that goal. Moreover, any deliberately retrogressive measures in that regard would require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources.**119**

This provision makes it clear that, while it may not be possible to realize the right to health immediately, a State Party may not simply ignore its obligations in respect of this right, but has to take deliberate, concrete and targeted steps towards expeditious and effective full realization thereof.120

In this regard, the UN Human Rights Commission states “Access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”121 General Comment 14 recognizes the

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120 Oehlke et al., “Access to Medicines and Human Rights.”

tripartite typology of interdependent duties with regards to the right to health. According to this typology, the right to health imposes three levels of obligations on State Parties, namely the obligations to respect, protect and fulfil the right to health.\textsuperscript{122}

The duty to respect requires State Parties to refrain from interfering directly or indirectly with the enjoyment of the right to health. This duty includes but is not limited to the obligation to refrain from denying or limiting equal access for all persons to preventive, curative and palliative health services; from marketing unsafe drugs and from limiting access to contraceptives. Denial of access to essential medicine or medical products would thus constitute a violation of this duty, as would any discriminatory allocation of medicines or funding for medicines.

The duty to protect requires State Parties to take measures that prevent third parties, including pharmaceutical companies, third-party states and international institutions such as the WTO, from interfering with article 12 guarantees.\textsuperscript{123} The importance of the duty to protect is even greater in respect of access to medicines, as pharmaceuticals are almost entirely manufactured and marketed by the private sector. This places the state under an obligation to ensure that pharmaceutical manufacturers do not limit the accessibility of essential drugs.

The duty to fulfill, which encompasses the duty to promote, entails an obligation to act positively in facilitating the actual realization of the right to health. As per the General Comment 14, this duty requires State Parties to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health. This duty places obligations on States Parties which include, but are not limited to, giving sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation; adopting a national health policy with a detailed plan for realizing the right to health including a policy on generics.\textsuperscript{124} Additionally, the duty to fulfill includes an obligation to provide the right when individuals or groups are unable to realize the right by their own means.

Failure to meet these basic standards for a dignified human existence prima facie


\textsuperscript{123} Oehlke et al., “Access to Medicines and Human Rights.”

\textsuperscript{124} Sebastião Salgado, Human rights for human dignity: A primer on economic, social and cultural rights (Amnesty International Publications, 2005).
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amounts to a breach of the obligations of the ICESCR. Only when a state can convincingly show that resources are “demonstrably inadequate” can its failure to fulfil these duties be justified. Such a minimum threshold is, however, country specific. In other words, the ways in which economic and social rights can be realized will vary with the nature of the national situation and the conditions applying there.

A. Practical Challenges to the Right to Access to Medicine in Kenya and South Africa

While Kenya has provided for the highest protection of the right to health, nationally it is yet to enact national health legislation in order to effectively implement the right to health. The lack of such a health law has impeded the development of a legal framework for the full realization of the right to health in Kenya, including access to essential medicines. Notwithstanding, the HIV and AIDS Prevention and Control Act is the only legislation that has expressly implemented the right to health care for persons living with HIV and AIDS. Secondly, Kenya has ratified most international human rights instruments enshrining the right to health. However, it is yet to ratify its Optional Protocol, which would amongst other things allow for individual communications. This has therefore severely impeded the protection of ESCRs internationally including the right to health.

Thirdly, the Patricia Asero case confirmed that the right to health enshrined in the Constitution and other legislations also encompasses access to essential medicines. Fourthly, under General Comment No 17 of the CESCRs, Kenya has the obligation to ensure that medicines’ prices are not exorbitant. Thus despite some of the socioeconomic challenges faced by the state, it is imperative that Kenya secures access to the affordable generic medicines for its patients since they are cheaper than branded medicines.


126 Salgado, Human rights for human dignity.


128 Larson et al., “ART Treatment Costs and Retention.”

In addition, Kenya’s provisions on parallel importation are ambiguous especially with regard to the Trademarks Act and the Pharmacy and Poisons Board. This is further exacerbated by lack of guidelines for parallel importation in Kenya.

South Africa for its part has the most elaborate constitutional and legislative provisions on the right to health and access to essential medicines nationally. The Constitution entrenches the right to health under its section. The National Health Act is also the principal legislation for the implementation of the right to health. Furthermore, regionally, South Africa has stronger commitment as illustrated by its membership to most of the core human rights instruments. This is a good development since South Africa has been at the forefront championing the agenda of the African Union (AU) in the continent by providing both technical and financial support. In addition, the TAC case confirmed the obligations of the government with regards to the right to health to make accessible essential medicines including Nevirapine in particular for the vulnerable poor South African mothers dependent on the public health system. It reiterated that the government’s program must be reasonable and comprehensive.\textsuperscript{130} Fifthly, South Africa is not bound by General Comment No 17 to protect medicines prices. However, it is Constitution and the court’s jurisprudence secures the right to health including affordable health care and essential medicines.\textsuperscript{131}

\section*{VI. Conclusion}

The explicit recognition of the highest attainable standard of health as a human right as opposed to a commodity has enabled many people in Africa to have access to essential medicine, by treating access to essential medicine as a right embedded within the right to health. The right to access to essential medicine as a fundamental human right has enabled millions of people in the African continent to have access to Anti-Retroviral drugs, and medicines for diseases such as tuberculosis, malaria, measles, and meningitis. This right has created a powerful authoritative basis for advocacy, as seen in Kenya and South Africa,


\textsuperscript{131} Ibid.
to fight for the marginalized and vulnerable in society and to create a useful framework and guidance to identify and analyze as well as respond to the underlying determinants of health (water, sanitation, food, nutrition, health occupational and environmental conditions, education, information, etc.). It also serves as a standard against which to assess government performance and accountability in the public health sector.

The landmark decision in the anti-counterfeit case has facilitated access to generic medicine for more than 430,000 people living with HIV in Kenya who are now on treatment.\textsuperscript{132} The decision has also had implications beyond Kenya, particularly in Uganda, where civil society has used it to influence Uganda’s parliament to order revision of the then-Anti-Counterfeit Bill 2010, which had provisions that would have affected access to generic medicines.\textsuperscript{133} In South Africa, the TAC was able to reduce the price of medicines, prevent hundreds of thousands of HIV-related deaths, but also to force significant additional resources into the health system and towards the poor.\textsuperscript{134} Despite some of the economic difficulties experienced by countries that have adopted this right in their national laws, the cases of Kenya and South Africa show that with the right policy and legal framework, it is possible to make this right a reality.

The cases also show that access to essential medicines is best achieved and guaranteed by the rights-based approach in national medicines policies and programs. A constitutional guarantee of access to essential medicines is an important indicator of government commitment to the progressive realization of the right to the highest attainable standard of health. Careful litigation has been helpful to encourage governments to fulfil these constitutional and international obligations. Success is possible and this should encourage others.

Health policy makers and the public health community should be aware of the increasing trend towards litigation. The Kenyan model was used by Uganda as the basis for revising its anti-counterfeit law, commitments have multiplied since 2008 and are now found in

\textsuperscript{132} “Anti-Retroviral Therapy,” National AIDS & STI Control Program (NASCOP), http://www.nascop.or.ke/.


22 constitutions. In 13 of these constitutions, states are duty-bound to fulfill medicines-related rights, some of which now use access to medicines terminology. The examples of constitutional text identified in the case of Kenya and South Africa can perhaps serve as a model to states motivated to achieve the universal right to health and access to essential medicine. Rather than the judiciary deciding over who should have access to which medicines, policy makers and legislators should ensure that human rights standards guide their health policies and plans from the start.

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