

“Government’s Constitutional Obligation to Provide Access to Affordable Medication under Section 27 of the Constitution.”

BY

MFANA PERCEIVE MASWANGANYI

Student No. 27541399

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Supervisor: Dr Ilze Grobbelaar-du Plessis

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Contents

Chapter 1.....	3
THE RIGHT OF ACCESS TO HEALTH CARE	3
1.1. Introduction.....	3
1.1. Research question	10
1.2. Problem statement	10
1.3. Methodology.....	11
Chapter 2.....	11
ACCESS TO HEALTH CARE IS AN INTERNATIONAL CONCERN.....	11
2.1. Introduction.....	11
2.2. International obligations	12
2.3. Factors affecting the price of medicines	16
2.4. Conclusion.....	17
Chapter 3.....	19
DOMESTIC VIEW: LEGISLATIVE AND OTHER MEASURES TAKEN BY THE SOUTH AFRICAN GOVERNMENT TOWARDS THE PROGRESSIVE REALISATION OF THE RIGHT TO ACCESS TO HEALTH CARE	19
3.1. Introduction.....	19
3.2. National Drug Policy for South Africa.....	20
3.3. Medicine and Related Substance Control Act, 101 of 1965 (“the 1965 Act”)	22
3.4. Patents Act 57 of 1978 (“the Patents Act”).....	26
3.5. Competition Act 89 of 1998 (“the Competition Act”)	31
3.6. Medical Schemes Act 131 of 1998 (“the MSA”)	36
3.7. National Health Insurance (“NHI”)	39
3.8. Other Measures	40
3.9. Conclusion.....	42
Chapter 4.....	44
PASSING MUSTER.....	44
4.1. Introduction.....	44
4.2. Analysis.....	44
4.3. Conclusion	49
CHAPTER 5	51
RECOMMENDATIONS	51
BIBLIOGRAPHY	54

Chapter 1

THE RIGHT OF ACCESS TO HEALTH CARE

1.1. Introduction

Access to health care is a fundamental right listed in Chapter 2 of the Bill of Rights of the Constitution of the Republic of South African, 1996 (“the Constitution”). Section 7 of the Constitution states that the Bill of Rights is the cornerstone of democracy in South Africa. It affirms the values of human dignity, equality and freedom. The State is obliged by section 7 to protect, promote and fulfil the rights contained in the Bill of Rights. According to section 8 of the Constitution, the Bill of Rights binds all organs of state and all natural and juristic persons, and it overrides all laws.

Section 27 (1) of the Constitution, which deals with health care, food, water and social security, reads as follows:

“Everyone has the right to have access to-

- (a) health care services, including reproductive health care,
- (b) ...
- (c) ...

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.

(3) No one may be refused emergency medical treatment.”

Section 27 and section 26 (dealing with the right to have access to adequate housing) are known as socio-economic rights, which are controversial in that some writers have

questioned their inclusion in the Bill of Rights, arguing that socio-economic rights have the potential to ‘politicise justice and judicialise politics’.¹ Furthermore, because the adjudication of socio-economic rights would involve budgetary issues it was argued that the judiciary is not qualified to handle this task because it lacks economic understanding of the issues involved. In *Ex parte Chairperson of the Constitutional Assembly*² the court rejected the arguments against subsuming socio-economic rights under the Bill of Rights. As Steinberg puts it, “the socio-economic clauses are concerned with the rights of classes of deprived people in the context of systemic injustice of our society.”³

Access to health care affirms people’s dignity and enables them to enjoy all the other fundamental rights.⁴ Whilst access to health care has benefits for individuals, it also substantially benefits the economic development of a nation.⁵ Bloom states that the 20th century has seen a great improvement in life expectancy due to a better understanding of germ theory, better hygiene and the development of vaccines and antibiotics.⁶ Bloom observes that when people’s health improves they have more disposable income and their spending patterns change accordingly.⁷ Bloom also states that when people live longer they begin to see the prospect of a retirement as real and therefore realise the need to save for retirement, thus contributing to growth of the country’s per capita

¹ Pieterse M “Coming to terms with Judicial Enforcement of Socio-Economic Rights” (2004) *SAJHR* 383 the author deals with many of the arguments which were raised against the justiciability of socio-economic rights.

² *Ex parte Chairperson of the Constitutional Assembly: In re Certification of the Constitution of the Republic of South Africa* 1996 (4) SA 744 (CC), the First Certification Decision.

³ Steinberg C “Can Reasonableness Protect the Poor? A Review of South Africa’s Socio-Economic Rights Jurisprudence” (2006) 123 *SALJ* 264.

⁴ *Soobramoney v Minister of Health, KwaZulu Natal* 1998 (1) SA 765 (CC), paragraph 54. In his minority judgement, Sachs J stated: “A healthy life depends upon social interdependence...” Committee on Economic, Social and Cultural Rights, General Comment 14 of 2000 states: “The right to health is closely related to and dependent upon the realization of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health.”

⁵ Bloom D E et al (2004) 11.

⁶ Bloom D E et al (2004) 10.

⁷ Bloom D E et al (2004) 11.

income.⁸ The relationship between health and economic development is becoming increasingly apparent from the literature.⁹ Healthy workers are the most productive workers as they take fewer days off and their output outstrips that of less healthy colleagues.¹⁰ It is submitted that in South Africa with its high unemployment rate people are more likely to look for work and are more likely to be hired when they are healthy. While the Constitution prohibits unfair discrimination¹¹ certain labour intensive jobs require a person to undergo a fitness test to be hired, so good health is at a premium in such instances.¹²

Thus there is a strong link between economic development which filters down to individuals and the right to access to health care. When a country's economic growth filters down to the individuals it gives them financial liberty, which affirms their right to dignity.¹³ Strauss and Horsten note that unaffordable medicine is not just a consequence of poverty but that it may also cause poverty.¹⁴

⁸ Bloom D E et al (2004) 11.

⁹ WHO and Health Action International: "Measuring Medicine Prices, Availability, Affordability and Price Components" 2nd Ed www.who.int/medicines/access/OMS_Mdicine_prices.pdf accessed 04/04/2015, The WHO, the Partnership for Maternal, Newborn & Child Health and University of Washington. A Global Investment Framework for Women's and Children's Health: Advocacy Brochure. Geneva, Switzerland, 2003, Health and Development: A Compilation of Articles from Finance & Development, International Monetary Fund, Washington, DC December 2004 and WHO and Health Action International, Price, Availability and Affordability: An International Comparison of Chronic Disease Medicines, Background Report Prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005.

¹⁰ WHO and Health Action International: "Measuring Medicine Prices, Availability, Affordability and Price Components" 2nd Ed www.who.int/medicines/access/OMS_Mdicine_prices.pdf accessed 04/04/2015, The WHO, the Partnership for Maternal, Newborn & Child Health and University of Washington. A Global Investment Framework for Women's and Children's Health: Advocacy Brochure. Geneva, Switzerland, 2003, Health and Development: A Compilation of Articles from Finance & Development, International Monetary Fund, Washington, DC December 2004 and WHO and Health Action International, Price, Availability and Affordability: An International Comparison of Chronic Disease Medicines, Background Report Prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005.

¹¹ Act 108 of 1996, section 9. Section 9 of the Constitution. See Citation's Act.

¹² Section 15 of the Occupational Disease in Mines and Works Act 78 of 1973 requires employees at controlled mines to have certificates of fitness.

¹³ Bloom DE et al (2004) 11.

¹⁴ Strauss Z & Horsten D "A Human Rights- Based Approach to Poverty Reduction: The Role of the Right of Access to Medicine as an Element of the Right of Access to Health Care" PER 2013 3

According to research¹⁵ conducted by the World Health Organisation (“WHO”), the economic consequences of poor health include unexpected increase in health expenditure, reduced functional capacity, and lost income or productivity, poor educational achievement which imposes an inhibiting factor on future income and saving rates, with the knock-on effect that an unhealthy nation tends to attract low domestic and foreign investment.¹⁶ The cumulative effect of all these factors would be very bad for economic growth.¹⁷ There is therefore a very strong case to protect and enforce socio-economic rights.

However, in order to enforce a right, it is important that the nature of the right be understood; as O’ Regan J puts it, the obligations imposed by the right and the liable parties must be well-defined.¹⁸ Section 27 (1) imposes a positive obligation on the state to provide access to health care. Section 27 (2) imposes a positive obligation on the state to provide access to health care progressively to the full practicable extent of the available resources.¹⁹ The state also has a negative duty to refrain from interfering with socio-economic rights.²⁰

The first case in which the Constitutional Court (“CC”) dealt with socio-economic rights was that of *Soobramoney v Minister of Health, KwaZulu Natal*,²¹ which hinged on the right of access to health care. It is respectfully submitted that the case did not do much to advance understanding of the right of access to health care, but it did give an indication of how the CC will look at socio-economic rights going forward. The CC noted that: “[w]e live in a society in which there are great disparities in wealth.”²² The CC went on to say that; “Millions of people are living in deplorable conditions and in great poverty. There is

¹⁵ WHO Guide to Identifying the Economic Consequences of Disease and Injury (2009), page 8.

¹⁶ WHO Guide to Identifying the Economic Consequences of Disease and Injury (2009), page 8.

¹⁷ WHO Guide to Identifying the Economic Consequences of Disease and Injury (2009), page 8.

¹⁸ *Mazibuko v City of Johannesburg* 2010 (4) SA 1 (CC), paragraph 46.

¹⁹ *Minister of Health and others v Treatment Action Campaign and others* Case CCT 8/02, paragraph 29.

²⁰ *Mazibuko v City of Johannesburg* 2010 (4) SA 1 (CC), paragraph 47.

²¹ 1998 (1) SA 765 (CC).

²²

high level of unemployment, inadequate social security, and many do not have access to clean water or to adequate health services.”²³

In this passage the CC recognised that South African society was and still is characterised by persistent and widespread poverty, which virtually precluded access to health care. The CC recognised that government is obliged by the Constitution to take remedial steps to provide health-care services for the millions who have no access to such services. The CC was also aware, however, that catering adequately for access to socio-economic services requires a balancing act with major budgetary implications. The CC again stated that: “[a] court will be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters.”²⁴

Some argue that these words signal reluctance to engage with budgetary matters. For example, Pieterse speculates that the CC was indicating the difficulty of being saddled with the obligation of being a “watchdog” over the enforcement of socio-economic rights.²⁵ However, the CC stated that the state has a constitutional duty to comply with obligations imposed on it by section 27 of the Constitution.²⁶

In *Government of the Republic of South Africa v Grootboom*²⁷ the CC laid down guidelines on how socio-economic rights were to be upheld and given practical substance in South Africa. The Court noted that although there is no question about the justiciability of economic rights the issue of implementation would have to be decided in a case-by-case basis. The matter was complicated by the CC’s refusal to define the right of access to

²³ Paragraph 8.

²⁴ 1998 (1) SA 765 (CC), paragraph 29.

²⁵ Pieterse M: “Coming to terms with Judicial Enforcement of Socio-Economic Rights” (2004) SAJHR 383- the author deals with many of the arguments which were raised against the justiciability of socio-economic rights. Page 401.

²⁶ *Soobramoney v Minister of Health, KwaZulu Natal*, paragraph 36.

²⁷ 2001 (1) SA 46 (CC).

adequate housing, stating that it was not within its terms of reference to give meaning to socio-economic rights. Furthermore, it dismissed a claim that there is a definable ‘core minimum’ to the substance of socio-economic rights as conceived in the Constitution and it held further that the executive was better placed to give meaning to socio-economic rights. This approach is known in legal circles as “deference”.²⁸

The CC has been criticized for this approach. Brand²⁹ observes that in performing their judicial review function judges must realise that they have to acknowledge their obligations not only towards other branches of government but towards citizens as well.³⁰

Twinomugisha³¹ writes that:

The judiciary can play an important role in the struggle to realise the right to health generally and the right of access to medicines in particular. Judicial strategies are important in a number of respects. Courts can clarify on the nature, scope and content of human rights, thereby enriching the jurisprudence in the area.

It will appear therefore that by refusing to define the content of the socio economic rights, the CC has missed an important opportunity in the enforcement of socio economic rights.

The test for government’s compliance with its constitutional socio-economic rights obligation was established in *Grootboom* when the CC decided that the test of reasonableness would be applied to decide whether a measure taken by government is in compliance with sections 26 or 27 of the Constitution. The question at issue would

²⁸ Pieterse M: “Coming to terms with Judicial Enforcement of Socio-Economic Rights” (2004) SAJHR 383- the author deals with many of the arguments which were raised against the justiciability of socio-economic rights, page 398.

²⁹ Brand D: “Judicial Deference and Democracy in Socio-Economic Rights Cases in South Africa” (2011) 22 SLR 614.

³⁰ Brand D: “Judicial Deference and Democracy in Socio-Economic Rights Cases in South Africa” (2011) 22 SLR 614.

³¹ Twinomugisha B “Implications of the TRIPs agreement for the Protection of the Right of Access to Medicines in Uganda” Malawi Law Journal 2008 253

therefore be whether the relevant measure is reasonable.³² However, Wilson and Dugard³³ argue that:

... if “reasonableness” is to add up to anything more than “the values, assumptions, and sensitivities” that the judges themselves bring “to the exercise of decision making, whether consciously or not” will require the Court to revisit some of its prior jurisprudence and reassess the manner in which it has conceptualized socio-economic rights litigation in its recent decisions.³⁴

According to the CC in *Grootboom*, a reasonable programme must clearly allocate responsibilities and tasks to different spheres of government and ensure that appropriate financial and human resources are available. Accordingly, the programme will be reasonable if it is capable of facilitating the realisation of the right in question. It is irrelevant to the test of reasonableness whether the State could have adopted better measures to achieve the realization of the right in question. The CC in *Grootboom* went on to state that:

[L]egislative measures by themselves are not likely to constitute constitutional compliance. Mere legislation is not enough. The state is obliged to act to achieve the intended result, and the legislative measures will invariably have to be supported by appropriate, well-directed policies and programmes implemented by the executive. These policies and programmes must be reasonable both in their conception and their implementation. The formulation of a programme is only the first stage in meeting the state’s obligation. The programme must also be reasonably implemented. An otherwise reasonable programme that is not implemented reasonably will not constitute compliance with the state’s obligations.³⁵

The test was developed further in the case of *Mazibuko v City of Johannesburg*³⁶ when the CC held that socio-economic rights are enforced in two ways: where government has

³² Government of the Republic of South Africa v Grootboom 2001 (1) SA 46 (CC), paragraph 41.

³³ Wilson S and Dugard J: “Taking Poverty Seriously: The South African Constitutional Court and Socio-Economic Rights” (2011) 22 SLR 664.

³⁴ Wilson S and Dugard J: “Taking Poverty Seriously: The South African Constitutional Court and Socio-Economic Rights” (2011) 22 SLR 664, page 672.

³⁵ The *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC), paragraph 42.

³⁶ 2010 (4) SA 1 (CC).

taken no measure to realize the right it will be ordered to do so, and where government has adopted unreasonable measures courts will order that they be reviewed.³⁷

And so in the case of *Minister of Health & another v New Clicks SA (Pty) Ltd & others*,³⁸ the CC recognized the right of government to provide measures which will bring about price reduction of drugs than they currently are. This gives the government the power to amongst others, regulate the price of medicine.

1.1. Research question

The research question that the study will address is the following: What are the legislative and other measures which the South African government has taken to progressively make drugs/medication affordable in order to ensure access to health care services in terms of section 27 of the Constitution?

1.2. Problem statement

Whilst it is accepted that the right of access to health care services includes the right to have access to affordable medication³⁹ the problem of “access” is compounded by the fact that the state does not produce medication. Thus, every legislative and other measure that the state intends to embark on in order to progressively realize the right to affordable medication must also respect the interest and/or rights of the pharmaceutical companies.

³⁷ *Mazibuko v City of Johannesburg* 2010 (4) SA 1 (CC), paragraph 67.

³⁸ [2006] JOL 17488 (CC).

³⁹ *Minister of Health v New Clicks SA (Pty) Ltd* 2006 (2) SA 311 (CC) paragraph 514 and 706.

The research will review the measures employed by government in pursuance of equitable access to health care in making medicines affordable. It is important to review these measures to ascertain if they are yielding the desired results. The research will include a discussion on the background, constitutional, legislative and/or policy measures. Having identified the legislative and policy measures taken, the research will investigate whether the legislative and policy measures in question meet the constitutional standard of reasonableness as set out in the case of *Grootboom*⁴⁰ and other case law.

1.3. Methodology

The research will review the Constitution, policy documents, legislations, articles written by different authors, international and South African research reports and case law reported.

Chapter 2

ACCESS TO HEALTH CARE IS AN INTERNATIONAL CONCERN

2.1. Introduction

In terms of section 39 (1) (c) of the Constitution when interpreting the Bill of Rights, a court, tribunal or forum must consider international law. International instruments and customary law provide a framework for interpretation of the Bill of Rights.⁴¹ However, it

⁴⁰ *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC).

⁴¹ *S v Makwanyane and another* 1995 (6) BCLR 665, paragraph 35.

may be directly applicable where the international obligation is binding on South Africa by virtue of legislation or other means specified under sections 231 to 235.⁴² The purpose of this chapter is to explore South Africa's international obligations in terms of various international instruments, which South Africa is a signatory to, and to identify factors that are internationally regarded as causes of high prices of medication which in turn prevent access to health care services.

2.2. International obligations

The WHO is the world's leading body in health matters.⁴³ WHO is an organ of the United Nations ("UN") and it was formed on the 7th of April 1948. The 7th of April is today celebrated the world over as World Health Day.⁴⁴ According to article 2 of the WHO's Constitution, its functions include the obligation "to act as the directing and coordinating authority on international health work."⁴⁵ WHO's Constitution further recognizes health in its preamble as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." The preamble to the WHO Constitution also states that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights..." that the WHO is responsible for with regard to global health matters. Its obligation in this regard is fulfilled through research and setting norms and standards.⁴⁶

On 10 December 1948 the United Nations General Assembly adopted the Universal Declaration of Human Rights (UDHR). The preamble of the UDHR states that the UDHR is a common standard for achievement for all peoples and all nations. Article 25.1 of the UDHR states that *everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services*. However, because the UDHR is a non-legal binding

⁴² Government of the Republic of South Africa v Grootboom 2001 (1) SA 46 (CC), paragraph 26.

⁴³ www.who.int/about/en, accessed on 30 August 2019.

⁴⁴ History of WHO: www.who.int/history/en/.

⁴⁵ Chapter II, Article 2.

⁴⁶ www.unbrussels.org/agencies/who.html, accessed on 03 October 2015.

instrument⁴⁷ the right to health is given the force of law by several other international legal instruments such as the: International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966,⁴⁸ Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) of 1979, Convention on the Rights of the Child (CRC) of 1989, and on the African regional level the African Charter on Human and Peoples' Rights, of 1981,⁴⁹ also known as the "Banjul Charter".

Article 12 (1) of the ICESCR states that *States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*. Article 12 (2) of the ICESCR mirrors article 2 (1) of the UDHR which requires state parties to take steps to the maximum of their available resources to ensure the progressive full realization of the rights recognized in the Covenant by appropriate means, including the adoption of legislative measures.

Part IV of the ICESCR bestows the administrative functions of the Covenant to the United Nations' Economic and Social Council (ECOSOC). In turn the ECOSOC formed the Committee on Economic, Social and Cultural Rights and tasked it with the monitoring of the ICESCR.⁵⁰ In order to assist State Parties in the interpretation and implementation of the ICESCR, the ECOSOC issues what it calls "*General Comments*". On 11 August 2000 the ECOSOC issued General Comment No.14 on the right to the highest attainable

⁴⁷ There are views that the Universal Declaration of Human Rights has become customary law. However, there is also a view that certain rights in the Universal Declaration of Human Rights, not all have reached the status of customary law; see O' Shea A (1998) *International Law and Organization: A Practical Analysis*: Butterworth, page 57.

⁴⁸ On 11 October 2012 President Jacob Zuma's cabinet announced that it approved a decision that South Africa accedes to the ICESCR (see Statement on Cabinet meeting of 10 October 2012 www.gcis.gov.za/content/newsroom/media-releases/cabstatements/11oct2012) The South African government finally ratified the ICESCR on 12 January 2015 after it was first signed by the former President, Nelson Mandela in 1994 (see a statement by the Human Rights Commission: Human Rights Commission welcomes ratification of International Covenant on Economic, Social and Cultural Rights 18 January 2015 www.gov.za/sahrc-welcomes-ratification-international-covenant-economic-social-an...

⁴⁹ The Right to Health, Fact Sheet N323, www.who.int/mediacentre/factsheets/fs323/2n/ accessed on 03/30/2015 and Health and Human Rights, International Covenant on Economic, Social and Cultural Rights, www.who.int/hhr/Economic_social_cultural.pdf accessed on 03/30/2015.

⁵⁰International Covenant on Economic, Social and Cultural Rights, www.who.int/hhr/Economic_social_cultural.pdf accessed on 03/30/2015.

standard of health.⁵¹ According to General Comment No.14 the right to health in all its forms and levels contains four essential interrelated elements. The first essential element is “**availability**” – which connotes sufficient quantities of facilities, goods and services and programmes.⁵² The second element is “**accessibility**”- which connotes reachability and affordability.⁵³ The third element is “**acceptability**”- which connotes respect for medical ethics and cultural appropriateness.⁵⁴ The fourth element is “**quality**”- meaning scientifically and medically appropriate.⁵⁵

State parties have obligations to respect, protect and fulfil in giving effect to the right to health.⁵⁶ A state party respects the right to health when it does nothing to interfere with its enjoyment. Protection implies that a State Party must ensure that non-state actors do not violate the right to health. Fulfilling the right to health requires the State Party to take positive steps within its available resources to ensure a full realization of the right.⁵⁷

According to ECOSOC, the right to health has a “core content” which means a minimum content of the right. The core content is the non-negotiable content of the right which every State Party must at least fulfil. According to ECOSOC it is the duty of a State Party to define what constitutes its right to the core content of health. Such content must include the adoption and implementation of a national public health strategy and plan of action, which covers the health concerns of the whole nation.⁵⁸ The public health strategy and

⁵¹ [11/08/200 E/C12/2004/4](#). (General Comments).

⁵² Paragraph 12(a).

⁵³ Paragraph 12 (b).

⁵⁴ Paragraph 12 (c).

⁵⁵ Paragraph 12 (d).

⁵⁶ [11/08/200 E/C12/2004/4](#). (General Comments) and The Right to Health, Fact Sheet N323, www.who.int/mediacentre/factsheets/fs323/2n/ paragraphs 3, 34.35 and 36. Accessed on 03/30/2015.

⁵⁷ [11/08/200 E/C12/2004/4](#). (General Comments) and The Right to Health, Fact Sheet N323, www.who.int/mediacentre/factsheets/fs323/2n/,_paragraph_30. Accessed on 03/30/2015.

⁵⁸ [11/08/200 E/C12/2004/4](#). (General Comments) and The Right to Health, Fact Sheet N323, www.who.int/mediacentre/factsheets/fs323/2n/,_paragraphs_43. Accessed on 03/30/2015.

plan of action must be reviewed periodically in a transparent and consultative manner. It must also have performance indicators to monitor progress.⁵⁹

The CEDAW protects women's right to health under Articles 10(h), 11(f), 12(1) and 14(2) (b). Article 12 obliges State Parties to take appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning. Article 14 (2)(b) obliges State Parties to protect rural women's right to have access to adequate healthcare facilities, including information counselling and services in family planning.

The CRC protects children's right to health under articles 3(3), 17, 23(3) and (4), 24, 25, 32, and 40(1). Article 24(1) obliges State Parties to recognise the right of the child to enjoy the highest attainable standard of health and facilities for the treatment of illness and rehabilitation of health and to ensure that no child is deprived of his or her right of access to such health care services.

The African Charter on Human and Peoples' Rights recognise the right to health under article 18 which states that the family shall be deemed the natural unit and basis of society and it shall be protected by the State, which shall also take care of its physical health and moral well-being.

At the United Nations Millennium Summit in September 2000 world political leaders adopted the Millennium Development Goals ("MDGs") aimed at improving health

⁵⁹ [11/08/200 E/C12/2004/4](http://www.who.int/mediacentre/factsheets/fs323/2n/). (General Comments) and The Right to Health, Fact Sheet N323, www.who.int/mediacentre/factsheets/fs323/2n/, paragraph 56. Accessed on 03/30/2015.

standards and halving poverty by 2015.⁶⁰ MDG 4 requires states to reduce child mortality, MDG 5 requires states to improve maternal health and MDG 6 requires states to combat HIV/AIDS, malaria and other diseases.

2.3. Factors affecting the price of medicines

Despite the obvious health benefits, people in developing countries still suffer from far higher rates of infectious diseases than their counterparts in developed countries with 99 % of all deaths caused by AIDS, TB and malaria occurring in developing countries.⁶¹ The non-communicable diseases⁶² are also wreaking havoc in the developing countries.⁶³ The WHO requires states to determine their priority diseases and come up with a list of essential drugs,⁶⁴ and when available and affordable, of quality, and with the appropriate usage essential medicines are expected to make a substantial positive impact on the disease burden of the state.

⁶⁰ WHO Macroeconomics and Health: Investing in Health for Economic Development, Report of the Commission on Macroeconomics and Health.

⁶¹ WHO and Health Action International: Measuring Medicine Prices, Availability, Affordability and Price Components 2nd Ed www.who.int/medicines/access/OMS_Mdicine_prices.pdf accessed 04/04/2015

⁶² Infectious diseases.

⁶³ Health and Development: "A Compilation of Articles from Finance & Development, International Monetary Fund", Washington, DC December 2004.

⁶⁴ "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines 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 adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility" (see WHO Policy Perspectives on Medicines: "Equitable Access to Essential Medicines: A Framework for collective Action" March 2004

According to research⁶⁵ accessibility of medicines is dependent on affordability. The WHO has discovered that usually, if medicines are provided in the public sector at no cost, the hospitals usually suffer from chronic stock shortages.

When patients are expected to pay for their medicines in the public sector, the prices are usually excessive.⁶⁶ By comparison hospitals in the private sector are usually fully stocked but the prices are even more excessive, ranging from three to 100 times the international reference price.⁶⁷ Affordability of medicines is itself influenced by factors such as **duties, taxes, mark-ups, distribution cost and dispensing fees, patents regulations, level of competition within the pharmaceutical industry and the level of domestic production of medicines.**⁶⁸ This research further states that 90% of the population in low and middle income countries pay for medicines out of their pockets due to **lack of social insurance** and insufficient subsidised services.⁶⁹

2.4. Conclusion

This chapter has established South Africa's international obligations with regard to the right of access to health care in virtue of various international obligations. This chapter also noted the major factors that are internationally regarded as reasons for high medicine prices that render medicines unaffordable and inaccessible to the population at large.

⁶⁵ Price, Availability and Affordability: An International Comparison of Chronic Disease Medicines, Background Report Prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005, page viii

⁶⁶ Price, Availability and Affordability: An International Comparison of Chronic Disease Medicines, Background Report Prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005, page viii

⁶⁷ Price, Availability and Affordability: An International Comparison of Chronic Disease Medicines, Background Report Prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005, page viii

⁶⁸ WHO and Health Action International: "Measuring Medicine Prices, Availability, Affordability and Price Components" 2nd Ed www.who.int/medicines/access/OMS_Mdicine_prices.pdf accessed 04/04/2015.

⁶⁹ WHO and Health Action International: "Measuring Medicine Prices, Availability, Affordability and Price Components" 2nd Ed, page 1: www.who.int/medicines/access/OMS_Mdicine_prices.pdf. accessed 04/04/2015.

Chapter 3

DOMESTIC VIEW: LEGISLATIVE AND OTHER MEASURES TAKEN BY THE SOUTH AFRICAN GOVERNMENT TOWARDS THE PROGRESSIVE REALISATION OF THE RIGHT TO ACCESS TO HEALTH CARE

3.1. Introduction

The *Minister of Health And Another v The New Clicks South Africa (Pty) Ltd*⁷⁰ the CC stated that as part of its health-care policy government is entitled to adopt measures to reduce medicine prices.

The purpose of this chapter is to explore the legislative and other measures which the South African government has taken over the years to enable its citizens and everyone in the country to have due access to health-care services. The chapter will begin by exploring the foundation of the government's response to section 27 (2) of the Constitution, which is the National Drug Policy.⁷¹ Most importantly, the chapter will seek to establish a link between the National Drug Policy and the WHO research revealing factors referred to in the previous chapter that cause high medicine prices.

The chapter will also explore the legislative measures adopted to achieve the objectives and address the concerns identified in the National Drug Policy. The chapter will achieve this by chronicling the objectives and the operations undertaken under legislative and other measures adopted by the state. Where reference is made to case law the aim is not necessarily to explore the legal principles in those cases, but to show the history of the

⁷⁰ Case CCT 59/04 2005 (2) SA 311 (CC), paragraph 32.

⁷¹ www.apps.who.int/medicinedocs/en/d/Js17744en/, accessed on 04 February 2016.

legislation and/or measure the challenges faced by the South African government in adopting and implementing the said legislation or measure.

3.2. National Drug Policy for South Africa

The South African National Drug Policy was adopted in 1996.⁷² Surprisingly it neither makes reference to the right of access to health care in the then newly adopted Constitution of the Republic of South Africa, 1996 (“the Constitution”) nor to the Interim Constitution of 1993. Nevertheless the policy is undoubtedly aimed at broadening the right of access to health care as envisioned under section 27 of the Constitution. The National Drug Policy recognizes that the South African health industry is divided into two sectors: a private sector, which serves about 20% of the country’s total population, and a public sector, which serves the rest of the population.⁷³ The private sector is mainly funded by medical aid schemes.⁷⁴

The fact that the health industry has been liberalized by allowing non-state actors to operate within it is generally supposed to extend health services, but attainment of that objective does not necessarily translate into accessibility. The fact that democracy has broken down walls that used to protect health facilities and services reserved for whites does not mean that the new-found openness of facilities will be accessible to all.⁷⁵ Opening up and expanding institutions and facilities is not enough, people need to be empowered in order to take advantage of the available health-care services. Empowering people might mean making information available and accessible but it also means making medicines and other services financially affordable to the masses. In this regard Fish and Ramjee observe that the 2005 Health Charter defines “access” as ‘having the capacity

⁷² www.apps.who.int/medicinedocs/en/d/Js17744en/, accessed on 04 February 2016.

⁷³ The South African National Drug Policy, Chapter 2, page 3.

⁷⁴ The South African National Drug Policy, Chapter 2, page 3

⁷⁵ Ha-Joon Chang (2010) 217.

and means to obtain and use an affordable package of health care services in South Africa in a manner that is equitable.⁷⁶

The South African National Drug Policy was adopted amid concerns about rising drug prices in international terms, irrational use of drugs, losses of drugs through malpractice and poor security, inefficient procurement, and logistic practices.⁷⁷ It is therefore no surprise that the South African National Drug Policy states that its goal “is to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and rational use of drugs by prescribers, dispensers and consumers.”⁷⁸

One of the health objectives of the South African National Drug Policy is “to ensure the availability and accessibility of essential drugs to all citizens”.⁷⁹ One of its economic objectives is “to lower the cost of drugs in both the private and public sectors.”⁸⁰ And one of its national development objectives is “to support the development of the local pharmaceutical industry and local production of essential drugs.”⁸¹

According to the South African National Drug Policy, accessibility will be achieved by “monitoring and negotiating drug prices and by rationalizing the drug pricing system in the public and private sectors, and by promoting the use of generic drugs.”⁸² Given that the promotion of generic drugs implies that the South African government look at its patent protection laws, it is surprising that the South African National Drug Policy is silent on this issue.

⁷⁶ Fish t & Ramjee F “Unaffordable Medical Scheme Contributions: A Barrier to Access to Private Health Cover in South Africa” South African Journal of Business Management 2007 29

⁷⁷ The South African National Drug Policy, Chapter 2, page 3.

⁷⁸ The South African National Drug Policy, Chapter 2, page 3.

⁷⁹ The South African National Drug Policy, Chapter 2, page 3.

⁸⁰ The South African National Drug Policy, Chapter 2, page 3.

⁸¹ The South African National Drug Policy, Chapter 2, page 4.

⁸² The South African National Drug Policy, Chapter 2, page 4.

The South African National Drug Policy provides for the formation of a Pricing Committee to be housed in the Department of Health.⁸³ The Role of the Pricing Committee is to monitor and regulate drug prices. According to the National Drug Policy, a non-discriminatory pricing system will be introduced and enforced if necessary; the wholesale and retail pricing percentage mark-up system will be replaced with a pricing system based on a fixed professional fee. A database will be developed to monitor the nationwide cost of drugs and compare prices with those in developing and developed countries. Price increases will be regulated and where there is a view that a pharmaceutical price of an essential drug is unacceptable, the state will make that drug available in the private sector at acquisition cost plus the transaction cost.⁸⁴

In line with ECOSOC's General Comment No 14, the South African National Drug Policy provides for the policy to be monitored and reviewed at regular intervals with a full evaluation occurring after every three years. However, the performance indicators were still to be compiled. Despite this preordained commitment on ECOSOC's part though, it was noted in the South African Health Review 2012/13 that no full review of the South African National Drug Policy had occurred.⁸⁵ However, the authors acknowledged that some provincial reviews of the health system had occurred.⁸⁶

3.3. Medicine and Related Substance Control Act, 101 of 1965 ("the 1965 Act")

In order to comply with its obligation in terms of section 27 of the Constitution, namely to take reasonable legislative steps within its available resources to ensure progressive realisation of the right to health care, the South African government through the

⁸³ The South African National Drug Policy, Chapter 4, page 9.

⁸⁴ The South African National Drug Policy, Chapter 4, page 9.

⁸⁵ Pharasi B and J Miot "Medicines Section and Procurement in South Africa" (SAHR 2012/13) page 178.

⁸⁶ Pharasi B and J Miot "Medicines Section and Procurement in South Africa" (SAHR 2012/13) page 178.

department of health amended the Medicine and Related Substance Control Act⁸⁷ through the Medicines and Related Substance Control Amendment Act 90 of 1997 (“the 1997 Act”)⁸⁸ to give the Minister of Health powers to regulate prices.

Clearly and Ross⁸⁹ note that during the apartheid regime the private health sector was very expensive in South Africa. The public health-care sector also had some of the highest prices compared to neighbouring states, so the 1997 Act was introduced to remedy this situation.⁹⁰ Section 15 of the 1997 Act was couched to provide for compulsory licensing and parallel importation of pharmaceutical products only.

The pharmaceutical companies brought a review application to challenge the constitutionality of the 1997 Act on 18 February 1998.⁹¹ Following this court challenge, the South African government was placed under pressure by the pharmaceutical industry and the United States government, which required guarantees that the South African government would fulfil its international obligation with respect to patent laws.⁹² In late 1999 the pharmaceutical industry announced that it was suspending its legal challenge to the 1997 Act and opened a new chapter of negotiations with the Department of Health with a view to settling the dispute. The negotiations collapsed and the Department of Health presented its Heads of Arguments on March 2001 with a somewhat changed stance on the interpretation of the 1997 Act. The Department of Health was no longer interested in compulsory licensing, but only argued that the 1997 Act should be understood to authorise parallel importation.

⁸⁷ Act 101 of 1965.

⁸⁸ Act 90 of 1997.

⁸⁹ S Cleary and D Ross “The 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry” A Game-Theoretic Analysis.

⁹⁰ S Cleary and D Ross “The 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry”: A Game-Theoretic Analysis.

⁹¹ Cleary S and Ross D “The 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry”: A Game-Theoretic Analysis.

⁹² Cleary S and Ross D “The 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry”: A Game-Theoretic Analysis.

Between 1999 and 2008 South Africa was in the quagmire of the AIDS epidemic,⁹³ so it came as no surprise when the Treatment Action Campaign (“TAC”) gained traction and was admitted as a friend of the court (*amicus curia*) on 06 March 2001.⁹⁴ Because of this, the case was postponed to 18 April 2001. On resumption of the case, the pharmaceutical companies and government announced that they have reached a settlement in terms of which government will seek measures to protect health in terms of Trade Related Aspects of Intellectual Property Rights (“TRIP”) and the pharmaceutical manufacturers agreed to support government in this regard.⁹⁵ The 1997 Act was amended by the Medicine and Related Substance Amendment Act⁹⁶ which came into operation in 2003.⁹⁷

On 30 April 2004 the Minister of Health, after consultation with the Pricing Committee,⁹⁸ promulgated Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances.⁹⁹ (“the regulations”). In terms of section 22G of the 1965 Act. The regulations introduced a pricing system in terms of which a “Single exit price (“SEP”)¹⁰⁰ will be set for the sale of each medicine that is sold by a manufacturer or importer.”¹⁰¹ This means that discounts to the SEP are prohibited.¹⁰² However, wholesalers are entitled

⁹³ Haywood M “The Price of Denial”, www.tac.org.za/Documents/PriceofDenial/doc, accessed on 31 August 2015. Also see: https://en.wikipedia.org/wiki/HIV/AIDS_in_South_Africa, accessed on 31 August 2015.

⁹⁴ Notice of Motion in the Transvaal Provincial Division, Case No. 4183/98.

⁹⁵ S Cleary and D Ross “The 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry “A Game-Theoretic Analysis.

⁹⁶ Act 59 of 2002.

⁹⁷ The Minister of Health And Another v The New Clicks South Africa (Pty) Ltd Case CCT 59/04 2005 (2) SA 311 (CC).

⁹⁸ The Pricing Committee is responsible for the determination and recommendation of prices of medicines to the minister of health in terms of Act 101 of 1965.

⁹⁹ 26304 of 2004-04-30.

¹⁰⁰ Is the price at which medicine or scheduled substance must enter the distribution chain. Wholesalers, distributors, and pharmacists are not allowed to put a margin on the medicine except adding a fee in terms of the relevant regulation.

¹⁰¹ The Minister of Health and Another v The New Clicks South Africa (Pty) Ltd Case CCT 59/04 2005 (2) SA 311 (CC).

¹⁰² This is line with the National Health Policy which stated under paragraph 4.1 that a government will introduce a non-discriminatory pricing system.

to add a logistic fee to the SEP and pharmacists are allowed a dispensing fee on top of the SEP.¹⁰³

The regulations¹⁰⁴ were challenged by the pharmaceutical industry on the basis that the Pricing Committee did not follow a proper procedure when hearing public comments and that section 22G did not allow the Minister of Health to make such regulations with regard to price control. The matter was heard by the Western Cape High Court in 2004 in *Pharmaceutical Society of South Africa v Minister of Health and Another*¹⁰⁵ and decided in favour of the Minister of Health.

The pharmaceutical companies led by “The New Clicks” applied for leave to appeal, but before the Western Cape could deliver its judgement the pharmaceutical companies approached the Supreme Court of Appeal (“SCA”) in *The Minister of Health and Another v The New Clicks South Africa*.¹⁰⁶ The pharmaceutical companies argued that the Western Cape High Court was taking too long to deliver its judgment. They argued that justice delayed is justice denied. The SCA agreed to hear the matter and found in favour of the pharmaceutical companies and set aside the regulations. The Minister of Health together with the Pricing Committee appealed the matter in the Constitutional Court. The Constitutional Court found in favour of the Minister of Health and the Pricing Committee by holding that the SCA was wrong in setting aside the regulations.

In 2011 Daleen Pretorius found in the course of research for a master’s degree¹⁰⁷ that in the first year of introducing the SEP and capped annual price increases, the price of medicines dropped by 22%.¹⁰⁸ However, there have been concerns that the SEP might lead to the closure of small pharmaceutical retailers based in rural areas. It has also been

¹⁰³ Regulation 10 of GG 38731 of 2015-03-23 read with section 22G (2) (b) of Act 101 of 1965.

¹⁰⁴ 26304 of 2004-03-30.

¹⁰⁵ *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another* 2005 (3) SA 231 (cc).

¹⁰⁶ *Pharmaceutical Society of South Africa v Minister of Health and Another* 2005 (6) BCLR 576.

¹⁰⁷ Pretorius D (2011) 36, [www.imsa.org.za/...impact%20of%20implementation%](http://www.imsa.org.za/...impact%20of%20implementation%20) accessed 07/04/2015

¹⁰⁸ Pretorius D (2011) 36, [www.imsa.org.za/...impact%20of%20implementation%](http://www.imsa.org.za/...impact%20of%20implementation%20) accessed 07/04/2015.

acknowledged that to assess the impact of the SEP on the viability of different kinds of pharmacies would be difficult.¹⁰⁹

It has to be stressed though that the size of the drop in price is not the issue, but how many more people who previously could not afford medicine are now able to. A price decrease could just be giving relief to those who already could afford without extending coverage. So a price decrease will only be meaningful if it extends coverage. This is not to downplay the relief which a lower price can provide to those who could afford medicine, but more especially to consider the relief to the poor so that even those who can afford the prices currently can be sure that they will be covered even if their fortunes change for the worse.

3.4. Patents Act 57 of 1978 (“the Patents Act”)

Many people are of the view that patents are the major cause of high prices of medicines. Writing on the Mediterranean Journal of Social Sciences Muswaka stated; “As a result of the monopoly created [by patents], the market is starved of competition and in the absence of strict price regulation; prices go up and stay high.”¹¹⁰

De Vos expressed the same view when he said “the biggest stumbling block to providing more people with better access to anti-retroviral therapy remains high drug prices, mainly due to the strict enforcement of patents.”¹¹¹

Vawda and Baker state that “central to efforts to conscientising and campaigning in the health context is an understanding of the role of intellectual property rights in making life-

¹⁰⁹ Gray AL. “Medicine Pricing Intervention - the South African Experience” (Southern Med Review) 2; 2:15-19.

¹¹⁰ Muswaku L “Mediterranean Journal of Social Sciences (MJSS) 2014 229.

¹¹¹ De Vos P “So Much To Do, So Little Done: The Right of Access to Anti-retroviral Drugs Post-Grootboom” Law, Democracy and Development 2003 83.

saving and life-enhancing medicines unaffordable in low-and middle-income countries.”¹¹²

However, Dr Eric Neohrenberg, the Director of International Trade and Market Policy and Director of Public Health Advocacy for the International Federation of Pharmaceutical Manufacturers and Associations disagrees. He points out that 95% of the pharmaceutical products on the WHO essential drug list are not patented anywhere in the world.¹¹³ He argues also that patents compel competitors to find new and innovative ways of treating diseases. He points out that since 1985 there has been 20 ARVs and nearly 60 drugs for the treatment of AIDS related infections.¹¹⁴ Despite this, the discussion below will show that patents were and are still are at the centre of medicine pricing and affordability in South Africa.

As a member of the World Trade Organization, South Africa is bound¹¹⁵ by the Agreement on TRIPS.¹¹⁶ South Africa therefore has international obligations to protect intellectual rights within its territory. Intellectual property in South Africa is protected in terms of the Patents Act¹¹⁷ and the Intellectual Property Laws Amendment Act.¹¹⁸

According to section 46 of the Patents Act, patents are protected for a period of 20 years. The usual rationale for protecting patents is that investors spend lot of resources in research and development (“R&D”) and therefore they need to be protected in order to recoup their investment and to make profit. This also encourages innovation without

¹¹² Vawda Y and Baker B “Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realising the Goal of Access to Medicines” AHRJ 2013 (13) 55.

¹¹³ “Patents Aid Access to Medicines” SA Pharmaceutical Journal 2008 68.

¹¹⁴ “Patents Aid Access to Medicines” SA Pharmaceutical Journal 2008 68.

¹¹⁵ Articles 1 and 2 of TRIPS.

¹¹⁶ RUGEGE U and Hassim A “Intellectual Property Regime and Access to Medicine - the Regulatory Gap” (Competition Commission Conference) 5-6 September 2013.

¹¹⁷ Act 57 of 1978.

¹¹⁸ Act 38 of 1997.

which the quality of life would be compromised. Section 4 of the Patents Act allows the Minister of Trade and Industry (“Dti”) to use a patent for inventions aimed at public purpose with the jurisdictional facts being that there must be an agreement between the Minister and the patentee. It also allows the minister to use the patent in breach of the agreement with the patentee if agreed by the Commissioner. Section 56 also allows the compulsory licensing if there is abuse of the patent, in which case it defines what will constitute abuse. The criticism against the South African government is that no attempt has ever been made to invoke sections 4 or 56 of the Patents Act despite the fact that health care remains a pipedream for many citizens who cannot afford medicines.¹¹⁹

Another problem is that the Patents Act makes no provision for compulsory licensing based on health concerns or that it does not include refusal to license where licensing would be for public health interest as an abuse of a patent. TRIPS, according to the Doha Declaration¹²⁰, TRIPS does not prohibit state parties from taking measures to protect public health.¹²¹ There is a view that South Africa has not used compulsory licensing because at the time when this issue gained exceptional prominence South Africa was in the midst of the AIDS epidemic and the then President Mbeki was questioning the existence of AIDS; consequently government could not support compulsory licensing for the purposes of utilising AIDS drugs.¹²²

The Patents Act provides that before it can be registered, a patent must be examined to see if it meets the requirements for a novelty, an inventive step and industrial application in terms of section 25. The Companies and Intellectual Property Commission (“CIPC”) has the mandate to register patents,¹²³ but it does not have capacity to examine patents

¹¹⁹ Cameron E Patents and Public Health “Principle, Politics and Paradox” www.britishacademy.universitypressscholarship.com accessed 07/04/2015.

¹²⁰ WT/MIN (01)/DEC/2, 20 November 2001 (01-5860).

¹²¹ RUGEGE U and Hassim “A Intellectual Property Regime and Access to Medicine - the Regulatory Gap” (Competition Commission Conference) 5-6 September 2013.

¹²² Cameron E Patents and Public Health “Principle, Politics and Paradox”, www.britishacademy.universitypressscholarship.com accessed 07/04/2015.

¹²³ Companies Act, 2008 Act 71 of 2008, sections 185 and 186.

before registrations, with the result that even patents that would strictly speaking not qualify for protection are wrongly registered and given protection for 20 years.¹²⁴ The Minister of Health, Dr. Aron Motsoaledi, stated that 30% of drugs which were denied patent protection in the United States of America (USA) on the basis that they were not new, were nevertheless granted intellectual property protection in South Africa, given the lack of capacity to examine patents applications. However, according to Doctors Without Borders, which is a non-governmental organisation, up to 40% of patents could be wrongly registered in South Africa.¹²⁵

When one considers the way the Department of Health abandoned the issue of compulsory licensing within its own legislation and the fact that section 4 of the Patents Act has not been utilized, there appears to be a lack of political will to go the route of compulsory licensing, perhaps for fear of discouraging foreign investment. We know that even though the Doha Declaration allows state parties to take steps to protect public health,¹²⁶ the USA government has discouraged countries from doing so through the use of bilateral agreements in terms of which developing countries are promised free access to the US market.¹²⁷

However, on 4 September 2013 the Minister of Trade and Industry published a General Notice¹²⁸ calling for comments on the new Proposed National Policy on Intellectual Property. The background to the policy states that South Africa has no national intellectual policy as a result different departments treat intellectual matters differently and therefore

¹²⁴ RUGEGE U and Hassim A “Intellectual Property Regime and Access to Medicine-the Regulatory Gap”; (Competition Commission Conference) 5-6 September 2013.

¹²⁵ Pretoria News (2014-03-14) 15.

¹²⁶ Article 31, read with Article 2 and 3 of the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

¹²⁷ Cameron E Patents and Public Health “Principle, Politics and Paradox” www.britishacademy.universitypressscholarship.com accessed 07/04/2015, and Cleary S and Ross D: The 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry: A Game-Theoretic Analysis.

¹²⁸ Draft National Policy on Intellectual Property (IP) of South Africa: A Policy Framework, GG 36816 of 2004-09-04.

there is a need to make uniform rules.¹²⁹ The proposed policy refers to the MDG of halving poverty and hunger and improving health and education.¹³⁰ The proposed policy objectives include improving access to intellectual property based on essential goods and services, particularly education, health and food and engendering confidence and attracting investment.¹³¹ The proposed intellectual property policy recommends that “South Africa must change the Patents Act to incorporate flexibility as contained in the TRIPS Agreement after the Doha Decisions”, and that the “Patents Act should be amended to be amenable to issues related to access to public health”. The proposed policy also recommends that “cabinet should consider approving the establishment of a substantive Search and Examination of Patents to have strong technologies.”¹³² This means that in the future before a patent is registered, it will first be subjected to a rigorous examination to check if it qualifies as a new invention.

In response to the Proposed Intellectual Policy, news leaked¹³³ that the Innovative Pharmaceutical Association of South Africa (“Ipassa”), an industry association representing drug manufacturers, decided to clandestinely oppose the proposed policy by forming a political organization which would be managed from the United States to delay implementation of the proposed policy. In effect the drug companies were opposing the delivery of cheaper medicines to the multitude that need health care. The current Minister of Health, Dr. Aaron Motsoaledi, called this plan by Ipassa “satanic and a plan for genocide”. In the wake of this scandal, which was revealed by Doctors Without Borders,

¹²⁹ Draft National Policy on Intellectual Property (IP) of South Africa: A Policy Framework, GG 36816 of 2004-09-04.

¹³⁰ Draft National Policy on Intellectual Property (IP) of South Africa: A Policy Framework, Government Gazette No. 36816, page 5.

¹³¹ 36816 of 2003-09-04.

¹³² Draft National Policy on Intellectual Property (IP) of South Africa: A Policy Framework, Government Gazette No. 36816.

¹³³ Business Day (2014-02-07), www.bdlive.co.za/business/healthcare/2014/02/07/ipasa-axes-committee-in-wake-of-patents-row, accessed on 23 January 2016.

¹³³ Section 3.

some executive members of the board of Ipasa resigned and some firms withdrew their membership of Ipasa.¹³⁴

The media scandal has since died down but it is not clear where government stands with regard to the proposed intellectual property policy since the Notice called for a 30 days deadline for submission of comments.

3.5. Competition Act 89 of 1998 (“the Competition Act”)

The Competition Act applies to all economic activity taking place in, or having an effect in South Africa.¹³⁵ This means the Competition Act has extraterritorial jurisdiction, meaning it also regulates conduct which took place in other countries, provided the conduct has an effect in South Africa. Anticompetitive conduct¹³⁶ that took place abroad can be punishable by the South African competition authorities if it has effects in South Africa. Manufacturers who import to South Africa and who are found to have entered into an agreement to fix prices abroad can be punished in South Africa if the products they import to South Africa are affected by the agreement to fix prices. One of the purposes of the Competition Act is to provide consumers with competitive prices and products.¹³⁷

The schema of the Competition Act is divided into eight chapters with the enforcement being located under chapter 2 in the form of restrictive practices and chapter 3 dealing with merger control. Section 4 of the Competition Act deals with restrictive horizontal practices which include price fixing, market allocation and collusive tendering (collectively referred to as collusive conduct). These restrictive horizontal practices are regarded as per-se violations. Once a per-se violation is proved, the respondent is not allowed to show

¹³⁴ Business Day (2014-02-07), www.bdlive.co.za/business/healthcare/2014/02/07/ipasa-axes-committee-in-wake-of-patents-row, accessed on 23 January 2016.

¹³⁵ Section 3.

¹³⁶ Act 89 of 1998, Section 73.

¹³⁷ Section 2.

a defence. Section 5 deals with restrictive vertical practices which substantially prevent or lessen competition in a market.

Section 8 deals with abuse of dominance conduct which includes excessive pricing, refusal to give a competitor access to an essential facility, inducement, bundling, refusal to supply, predatory pricing, buying-up a scarce supply of intermediate goods or resources required by a competitor and general exclusionary conduct. Section 9 deals with price discrimination and section 10 provides for exemption application which allows firms to apply to be exempted from the application of chapter 2 provided they meet the set requirements.

The Competition Commission of South Africa, established in terms of section 19 of the Competition Act, is the primary enforcer of the Competition Act, tasked with investigating all prohibited practices.¹³⁸ Complaints must be sent to the Competition Commission which must investigate prohibited practices within a year unless the period is extended on agreement with the complainant.¹³⁹ After investigating the matter, the Competition Commission must refer the matter to the Competition Tribunal for adjudication or issue a notice of non-referral.¹⁴⁰ If at the end of the year the Competition Commission has neither issued a non-referral nor extended the investigation period, is the complaint presumed to be non-referred.¹⁴¹ A notice of non-referral gives the complainant an opportunity to refer the complaint to the Competition Tribunal on her/his own.¹⁴² The decision of the Competition Tribunal may be appealed to the Competition Appeals Court,¹⁴³ which has the status of a high court.¹⁴⁴

¹³⁸ Section 21 of the Competition Act 89 of 1998.

¹³⁹ Section 50 of the Competition Act 89 of 1998.

¹⁴⁰ Section 50 of the Competition Act 89 of 1998.

¹⁴¹ Supreme Court of Appeal judgment in *Competition Commission v Yara and Others* Case No. 784/12.

¹⁴² Act 89 of 1998, Section 50.

¹⁴³ Act 89 of 1998, Section 37.

¹⁴⁴ Act 89 of 1998, Section 36.

In prosecuting prohibited practices specified under sections 5, 8 and 9 the market must be defined. A market is defined in terms of product and geography. Defining a product market is a function of both economics and law. The Competition Commission has experienced great success in prosecuting collusive conduct due to its Corporate Leniency Policy,¹⁴⁵ which allows a firm involved in collusive conduct to come forward with information against its co-conspirators in exchange for immunity.¹⁴⁶ On the other hand, it has not been plain sailing when it comes to abuse of dominance cases which require intricate economic analyses.¹⁴⁷ The Competition Act does not make provision for compulsory licensing of intellectual property.

However, it is theoretically possible for the Competition Tribunal to order compulsory licensing under section 8 (c) which deals with general exclusionary conduct as it is done in the European Union¹⁴⁸ and/or under section 8(b) which deals with refusal to give a competitor access to an essential facility when it is economically feasible to do so. The Competition Act defines “essential facility” as a resource or infrastructure that cannot reasonably be duplicated.¹⁴⁹ A patent cannot reasonably be duplicated when it still enjoys legal protection. The Competition Appeal Court¹⁵⁰ has ruled that the word “resource” does not include products, goods or services. It will therefore be interesting to see whether the Competition Tribunal and the Competition Appeal Court will interpret “resource” and limit it to only an input to the exclusion of patents.

It is also possible to have a drug price declared an “excessive price” and therefore prohibited conduct. However, this is not an easy exercise. The Competition Commission

¹⁴⁵ www.compcom.co.za/corporate-leniency-policy, accessed on 04 February 2016.

¹⁴⁶ In its 2012/13 financial year the Competition Commission targeted to consider 18 applications of Corporate Leniency but it considered 35. It also met its target to refer 10 cases to the Competition Tribunal. (see the 2012/13 Competition Commission Annual Report).

¹⁴⁷ In its 2012/13 financial year the Competition Commission targeted to refer two cases to the Competition Tribunal but it did not refer even a single case. (see the 2012/13 Competition Commission Annual Report).

¹⁴⁸ Fine F “European Community Compulsory Licensing Policy: Heresy versus Common Sense Symposium on European Competition Law”, *Northwestern Journal of International Law & Business*, Volume 24, Issue 3 Spring.

¹⁴⁹ Act 89 of 1998, Section 1.

¹⁵⁰ *Glaxo Wellcome (Pty) Limited and others v National Association of Pharmaceutical Wholesalers and Others*, Case No. 15/CAC/Feb02.

has never succeeded in proving an excessive price case. The Competition Act defines an “excessive price” as a price for a good or service that bears no reasonable relation to the economic value of that good or service.¹⁵¹

In 2009 parliament amended the Competition Act by passing the Competition Amendment Act¹⁵² (“the Competition Amendment Act”) to address, amongst others, the question of concurrent jurisdiction with other regulators, provide for criminal penalties for those who engage in collusive conduct, and provide for market enquiries. The Competition Amendment Act has been assented to and signed by the president, but there has been no date set for it to become effective. However, a section dealing with market enquiries has already come into operation through a Government Notice.¹⁵³ This was clearly intended to allow the Competition Commission to hold its intended market inquiry into the private health sector on the basis of a legally binding provision as opposed to its previous market enquiry on the banking sector which was on a voluntary basis.

In May 2013 the Competition Commission published the Draft Terms of Reference on the market inquiry on the private health sector and requested public comment. Organizations such as the Board of Healthcare Funders,¹⁵⁴ Discovery Health,¹⁵⁵ Hospital Association South Africa¹⁵⁶ and Life Group¹⁵⁷ criticized the non-inclusion of the pharmaceutical drug manufacturers. Discovery Health argued that roughly 20% of medical schemes’ expenditure goes to medicines. Furthermore, Discovery Health was of the opinion that generic medicines are also not affordable as there is only a small differential between the price of a generic and patent product. Discovery further argued that in South Africa generic medicines enter the market at 20% to 30% discount to the originator product, as

¹⁵¹ See Competition Appeal Court judgment: *Mittal Steel South Africa and others v Harmony Gold Mining Company Ltd and another*, Case No. 70/CAC/Apr07 and Competition Tribunal judgment: *The Competition Commission v Telkom SA LTD*, Case No. 11/CR/Feb04.

¹⁵² Act 1 of 2009.

¹⁵³ 36221 of 2013-03-08.

¹⁵⁴ Patel RH: Submission to the Competition Commission, Letter dated 25 June 2013.

¹⁵⁵ Broomberg J: Submission to the Competition Commission, Letter dated 24 June 2013.

¹⁵⁶ Bomela D: Submission to the Competition Commission, Letter dated 21 June 2013.

¹⁵⁷ Unsigned submission to the Competition Commission, Letter dated 23 May 2013.

opposed to the United States, where generic medicines enter the market at about 80% to 90% discount.

The *Who Owns Whom Report*¹⁵⁸ notes that competition between generic manufacturers and the originator products drives the manufacturers to intensify research and development in order to come up with new products which will be protected by patent laws and be insulated from competition for 20 years. The Report also says that there is strong competition between generic manufacturers and originator products. If figures submitted by Discovery to the Competition Commission regarding the level at which generic medicines enter the market in South Africa there can hardly be strong price competition between the generic manufacturers and originator products, or even amongst generic medicine manufacturers themselves.

Surprisingly, section 27¹⁵⁹ supported the Competition Commission's Draft Terms of reference in excluding the pharmaceutical drug manufacturers citing issues such as limited time and resources to cover the broad health industry. In November 2014, the Competition Commission published the final Terms of Reference for the Market Inquiry into the private health-care sector. The final Terms of Reference include "the relationship between pharmaceutical manufacturers, logistics services, health professionals, hospitals and hospital groups, doctors, and retail pharmacy as a systemic cost driver" and "the pricing and demand for new technology entering the health market involving, inter-alia, medicines, equipment, and pathology and their role as systemic cost drivers."

¹⁵⁸ The Pharmaceutical Industry Siccocode 33550, 61394a & 62310a.

¹⁵⁹ An NGO which describe itself as a public law center that seeks to influence and use the law to protect, promote and advance human rights.

The final market inquiry report was expected on 30 November 2015, however, the deadline has since been extended to December 2016.¹⁶⁰ It remains to be seen how the market inquiry will impact on affordability and improve access to medication.

3.6. Medical Schemes Act 131 of 1998 (“the MSA”)

The MSA establishes the Council for Medical Schemes (“the Council”), which is the regulator for medical schemes. In terms of section 7 of the MSA the Council has the mandate to protect the interest of the beneficiaries of medical schemes at all times. The Council is also tasked to control and coordinate the functioning of medical schemes in a manner that is complementary with the national health policy, and to investigate complaints and settle disputes in relation to the affairs of medical schemes.¹⁶¹ The Council has the powers in terms of section 8 of the MAS to approve the registration, suspension, and cancellation of registration of medical schemes or benefit options.¹⁶²

Section 29 (1) (o) of the MSA provides that medical schemes’ rules may be couched to provide for the scope and level of minimum benefits that are to be available to beneficiaries. Section 29 (1) (p) provides that no limitation shall apply to the reimbursement of any relevant health service obtained by a member of a medical scheme from a public hospital where this service complies with the general scope and level as contemplated in section 29(1) (o) and may not be different from the entitlement in terms of a service available to a public hospital patient.

According to Regulation 8 of the MSA ¹⁶³ all medical scheme benefit options must pay in full, without co-payment or the use of deductibles, the costs of diagnosis and care relating

¹⁶⁰ Business Day (2015-10-20), www.bdlive.co.za/business/healthcare/2015/10/2015/competition-commission-extends-private-healthcare-inquiry-timetable, accessed on 23 January 2016.

¹⁶¹ Section 7.

¹⁶² Section 8.

¹⁶³ 20556 of 2003-10-06.

to the prescribed minim benefit (“PMB”) conditions.¹⁶⁴ PMBs include any emergency medical condition.¹⁶⁵ Payment for PMBs may not be deducted from members’ savings.¹⁶⁶

This means that every medical scheme must pay in full for conditions which are regarded as PMBs, as well as for emergency conditions. According to Annexure A to the MSA there are more than 270 medical conditions and 26 chronic diseases which are regarded as PMBs.¹⁶⁷ In this regard, Regulation 7 of the MSA defines an “emergency condition” – as the “sudden and, at the time, unexpected onset of a health condition that requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily function or serious dysfunction of a bodily organ or part or would place the person’s life in serious jeopardy”.

The inclusion of diagnosis, treatment and care cost in PMBs ensures that members of medical schemes are also entitled to medication at no additional cost. PMBs were designed to protect members of medical schemes from financial ruin due to high cost of health care and to prevent dumping of medical-schemes patients from private hospitals to public hospitals once they have exhausted their medical aid cover.¹⁶⁸

Some of the criticism against PMBs include that they have made the cost of medical aid unaffordable – medical-schemes options are too costly because they factor in the cost of PMBs. Medical schemes claim that PMBs are costly for them and can lead to their bankruptcy.¹⁶⁹ There is also a view that medical scheme members lack information about

¹⁶⁴ Regulation 8.

¹⁶⁵ Regulation 8.

¹⁶⁶ Regulation 8.

¹⁶⁷ Arnold M “Levelling the Playing Field with the Aid of PMBS” (CMS News issue 1), April 2014.

¹⁶⁸ du Preez L “PMBS and the Private Healthcare Consumer”, (CMS News issue 1), April 2014.

¹⁶⁹The Amendment to Regulation 8 of the Medical Schemes Schemes Act, what does it mean, <http://hsf.org.za/resource-centre/hsf-briefs/the-amendment-to-regulation-of-the-medical-schemes-act>, accessed 04 September 2015. Read together with a newspaper article written by Catharine Child entitled: Court battle of medical schemes’ bid to cut patient benefits: <http://www.timeslive.co.za/local/2015/06/19/Court-battle-over-medical-aid-bid-to-cut-patient-benefits>.

Accessed 06 September 2015.

PMBs and as a result end up being robbed of their cover by medical schemes.¹⁷⁰ There are also allegations of abuse by service providers who bill non-PMB diseases as PMBs in order to secure full payment by the medical schemes.¹⁷¹ However, there is general agreement that these issues can be managed and that PMBs are a necessary tool to ensure access to health care.¹⁷²

It was reported that the Council is investigating the possibility of introducing a low cost benefit option (“LCBO”) which will cover about 15 million people who currently cannot afford medical aid.¹⁷³ It was reported that the LCBO will cover people of certain income brackets. In order to introduce this LCBO medical schemes may be exempted fully or partially from complying with PMBs and other provisions of the MSA. The Council has called for the submission of views from industry players.¹⁷⁴ It remains to be seen how the issue of PMBs will be handled because as we have seen, they serve a very important purpose and it will be unfortunate if 15 million people who might join the LCBO will not be covered for PMBs.

Medical schemes only cover 16.2 % of the population in South Africa.¹⁷⁵ According to the National Health Insurance Policy the medical scheme industry is not sustainable. It has gone from 180 medical schemes in 2001 to about 102 in 2009.¹⁷⁶ At the moment there is about 83 medical schemes left in the industry.¹⁷⁷ According to the National Health Insurance Policy this attrition is caused by the over pricing of health care.¹⁷⁸

According to Fish and Ramjee private health care providers increased their cost by more than the inflation rate resulting in the concomitant increase of health covers by medical

¹⁷⁰ Du Preez L “PMBS and The Private Healthcare Consumer” (CMS News issue), April 2014, page 7.

¹⁷¹ De Villeirs A “Prescribed Minimum Benefits” (CMS News issue 1), April 2014, page 17.

¹⁷² “CMS News issue “1, April 2014.

¹⁷³ www.news24.com/health24/medical-schemes-on-the-horizon-20150930.

¹⁷⁴ The Star (2015-03-31)

¹⁷⁵ National Health Insurance In South Africa: Policy Paper, page 11.

¹⁷⁶ National Health Insurance In South Africa: Policy Paper, page 11.

¹⁷⁷ Council for Medial Schemes (2015): Annual Report- 15 years on the pulse.

¹⁷⁸ National Health Insurance In South Africa: Policy Paper, page 11.

schemes.¹⁷⁹ According to Gray and Matsebula medicines are the biggest cost drivers in the private sector.¹⁸⁰ Fish and Ramjee argue that the Medical Schemes Act has done nothing to improve affordability of cover and to ensure access to health care.¹⁸¹

3.7. National Health Insurance (“NHI”)

National Health Insurance is in line with the National Health Policy which aims to increase equity in the provision of health care for all.¹⁸² In August 2011 the Department of Health released a Green Paper on the NHI.¹⁸³ The NHI is aimed at ensuring that all South Africans, as well as permanent residents, have access to appropriate, efficient and quality health services. The NHI is based on seven principles. They are the right to access in terms of section 27, social solidarity, effectiveness, appropriateness, equity, affordability and efficiency.

An objective of the NHI is to provide improved access to quality health services for all South Africans, irrespective of whether they are employed. The NHI states that it will increase socio-economic benefits, such as: increased output, which is achieved in that a healthy person works more efficiently; increased ‘work life’ for the same reason, as well as and a broader knowledge base in the economy.¹⁸⁴

The NHI is to be phased in within a period of 14 years.¹⁸⁵ In March 2012 the Minister of Health announced 10 pilot districts for the NHI. It is too early to judge whether the NHI is effective or not.

¹⁷⁹ Fish t & Ramjee F “Unaffordable Medical Scheme Contributions: A Barrier to Access to Private Health Cover in South Africa” South African Journal of Business Management 2007 29

¹⁸⁰ Gray A & Matsebula T “Drug Pricing” SAHR 2000 201

¹⁸¹ Fish t & Ramjee F “Unaffordable Medical Scheme Contributions: A Barrier to Access to Private Health Cover in South Africa” 2007 South African Journal of Business Management 29

¹⁸² National Health Insurance In South Africa: Policy Paper, page 3.

¹⁸³ Health: Update on Progress and Achievements in 2012/13, www.gov.za/issues/health, accessed on 14/04/2015.

¹⁸⁴ National Health Insurance in South Africa, Policy Paper, page 19.

¹⁸⁵ National Health Insurance in South Africa, Policy Paper, page 4.

3.8. Other Measures

Since 1988 the procurement of medicines in South Africa was coordinated by the Coordinating Committee for the Provisioning of Medical Suppliers (“COMED”) which was located in the Department of Health. However, the tenders for the supply of the medicines were awarded by the National Treasury. In 2009 the Department of Health took over the responsibility of coordinating the procurement¹⁸⁶ of medicines on behalf of the provinces and the awarding of tenders, and placed these responsibilities under the Central Procurement Agency (“CPA”)¹⁸⁷.

Consequently the Department of Health could use its buying power to negotiate discounts on the prices of medicines and was able to make the following savings in 2012/13:¹⁸⁸

- R69 million on TB drugs
- R169 million on antibiotics
- R70 million on oncology medication
- R69 million on injectable
- R3 million on drops and inhalers
- R105 million on tablets

According to a note submitted by the South African Government to the OECD Competition Committee the total sale of pharmaceuticals in 2013 was about R20bn.¹⁸⁹ The South African manufacturers mainly produce generic medication and the multinationals produce

¹⁸⁶ This measure is in line with paragraph 6.2 of the National Health Policy which states that procurement of medicine will be undertaken at national level using national and international tendering in order to procure at the best possible prices.

¹⁸⁷ Pharasi B and J Miot “Medicines Section and Procurement in South Africa” (SAHR 2012/13).

¹⁸⁸ Health: Update on Progress and Achievements in 2012/13, www.gov.za/issues/health, accessed on 14/04/2015, also see; Pharasi B and J Miot: Medicines Section and Procurement in South Africa (SAHR 2012/13).

¹⁸⁹ Generic Pharmaceuticals, A Note by South Africa, DAF/COMP/WD (2014)68, 18-19 June 2014.

originator products.¹⁹⁰ Between 1995 and 2010 about 37 pharmaceutical plants closed down.¹⁹¹

The local pharmaceutical companies are finding it hard to compete with imports from countries like India due to lack of custom protection.¹⁹² However, the Department of Trade and Industry says that the tax incentive scheme known as Strategic Industrial Project (“IP”) is not entirely fruitless as regards revitalising the local manufacturing sector but noted that recovery was very slow.¹⁹³ SIP is given under the Income Tax Acts,¹⁹⁴ in terms of section 12G dealing with additional investment allowance in respect of industrial assets used for qualifying strategic industrial projects.¹⁹⁵

On 10 February 2012 the DTi announced a joint venture between a state-owned company called Pelchem (Pty) Ltd and a Swiss company called Lonza. The joint venture was called “Ketlaphela”. Ketlaphela was to be the first South African pharmaceutical company to manufacture Active Pharmaceutical ingredients (“APIs”) for Anti-Retroviral Medicines (“ARVs”).¹⁹⁶

Ketlaphela’s aim was to supply cost-effective drugs to the government and to ensure the security of supply by reducing South Africa’s dependence on drug imports.¹⁹⁷ On 24 May 2013 Business Day, a daily newspaper, reported that government was looking for a new

¹⁹⁰ Industrial Policy Action Plan: Economic Sectors and Employment Cluster; IPAP 2013/14-2015/16.

¹⁹¹ Pharasi B and J Miot “Medicines Section and Procurement in South Africa” (SAHR 2012/13).

¹⁹² Industrial Policy Action Plan: Economic Sectors and Employment Cluster; IPAP 2013/14-2015/16.

¹⁹³ Industrial Policy Action Plan: Economic Sectors and Employment Cluster; IPAP 2013/14-2015/16.

¹⁹⁴ Act 58 of 1962.

¹⁹⁵ Applications for qualifying projects are sent to and approved by the Dti and administered by the South African Revenue Services (SARS).

¹⁹⁶ Media Statement by the South African Government on the Establishment of a Pharmaceutical Manufacturing Plant in South Africa, www.thedti.gov.za/editmedia.jsp?id=2327.

¹⁹⁷ Media Statement by the South African Government on the Establishment of a Pharmaceutical Manufacturing Plant in South Africa, www.thedti.gov.za/editmedia.jsp?id=2327, accessed on 16/04/2015, also see; Sapa: SA to Build R1.6bn pharmaceutical plan Business Day 13 February 2012.

investor after Lonza pulled out of the joint venture and brought it to a screeching halt.¹⁹⁸ On 17 February 2015 the Business Day reported that government had given up trying to find an investor for the joint venture and was planning to enter the market on its own.¹⁹⁹

On 13 April 2015 the Business Day reported that the Minister of Health, Dr. Aaron Motsoaledi, had told a gathering of doctors at the University of Pretoria that the Department of Health in collaboration with the Council for Scientific and Industrial Research (“CSIR”) would soon be launching a health information system in the public and private health sector in order to pool together resources under the NHI.²⁰⁰ The system would also prevent patients from hoarding medicines. Patients will not be able to ‘pub-crawl’ (ie. visit a chain of) health centres to collect the same medicines without the irregularity becoming noticeable in the system.²⁰¹

Regulation 9.3 of Preferential Procurement Regulations,²⁰² dealing with the Promotion of Local Contents and Production of new Preferential Procurement, is also used to give preference to local manufacturers of drugs²⁰³ in state procurement.²⁰⁴

3.9. Conclusion

¹⁹⁸ Business Day (2013-05-24), www.bdlive.co.za/business/healthcare/2013/05/24/setback-for-state-aids-drugs-pan...accessed on 23 January 2016.

¹⁹⁹ Kahn T: Wary Investor Wound State’s Drug Plans.

²⁰⁰ Business Day (2015-04-13), www.bdlive.co.za/national/health2015/04/13/motsoaledi-aims-for-health-data-on-tap.

²⁰¹ Business Day (2015-04-13), www.bdlive.co.za/national/health2015/04/13/motsoaledi-aims-for-health-data-on-tap.

²⁰² 34350 of 2011-06-08.

²⁰³ This measure is in line with paragraph 6.5 of the National Drug Policy which aims at increase self-sufficiency.

²⁰⁴ Industrial Policy Action Plan: Economic Sectors and Employment Cluster; IPAP 2013/14-2015/16.

This chapter has identified the legislative provision and other measures ie. the Nation Drug Policy, procurement measures and health insurance that the state has brought into play to progressively provide access to health-care services in keeping with the fundamental right to which all and sundry are constitutionally entitled. The chapter has identified factors that enable or block people’s access to health-care services in compliance or contravention of the National Drug Policy and the legislative measures adopted to ensure such access. The next chapter will be devoted to assessing the effectiveness of measures in achieving due observance of the relevant right.

Chapter 4

PASSING MUSTER

4.1. Introduction

The purpose of this chapter is to assess the legislative and other measures taken by government to bring about access to health care in line with section 27 of the Constitution. In particular, the chapter will assess all the measures discussed above. To that end the first step will be to take cognisance of the CCs jurisprudence on socio-economic rights, followed by considering how the CC treats cases involving socio-economic rights. The test established by the CC in various socio-economic rights cases to assess the legislative and other measures identified above to see if they meet the constitutional requirements will then be applied.

4.2. Analysis

To establish if government has succeeded in adopting measures which reduce the price of medicine we need not look further than the National Health Insurance Policy Paper which states that “[a]ttempts to reform the health system have not gone far enough to extend coverage to bring about equity in healthcare.”²⁰⁵ “Equity” is defined as “a system that ensures that those with the greatest health need are provided with timely access to health services.”²⁰⁶ The Policy document identifies those who currently do not have access to health care as being women, children, and the elderly and low income

²⁰⁵ National Health Insurance In South Africa: Policy Paper, page 6.

²⁰⁶ National Health Insurance In South Africa: Policy Paper, page 17.

groups.²⁰⁷ What we have learnt from the *Grootboom* case is that a measure that fails to provide relief to those who desperately need access to health care will not pass muster.

What then are we to make of the price reduction which came as the result of the SEP, the cost savings which came as a result of centralised purchasing by the Department of Health, and the increased life expectancy reported by Statistics South Africa as a result of extended coverage of ARVs?²⁰⁸ According to the National Health Insurance Policy Paper South Africa is mainly burdened by four diseases: HIV/AIDS and TB, maternal, infant and child mortality, non-communicable diseases and injury and violence.²⁰⁹ Since the Department of Health's central purchasing has only been used in the purchasing of ARVs, the burden of other diseases has not been addressed, with the result that a large number of people who need it are still not covered.

In *Grootboom* the Constitutional Court stated that “[i]t may not be sufficient to meet the test of reasonableness to show that the measures are capable of achieving a statistical advance in the realization of the right.”²¹⁰ The Court proceeded to say “[i]f measures, though statistically successful, fail to respond to the needs of those most desperate, they may not pass the test.”²¹¹ My view is that government measures have been able to achieve some value in reducing numbers but for large numbers nevertheless failed to provide desperately needed cover.

²⁰⁷ National Health Insurance In South Africa: Policy Paper, page 12.

²⁰⁸ Statistical Release P0302: Mid-year Population Estimates 2014- In releasing the statistics, Statistic South Africa stated: According to the report, “*life expectancy at birth stands at 61 years, having increased from an estimated 52 years in 2005. The rise in life expectancy can be attributed to two important trends: first, the number of AIDS related deaths is estimated to have decreased from 363 910 deaths in 2005 (51% of all deaths) to 171 733 deaths in 2014 (31% of all deaths). This is attributable to the increased rollout of antiretroviral therapy (ART). Second, the infant mortality rate (IMR) has fallen from an estimated 58 infant deaths per 1 000 live births in 2002 to 34 infant deaths per 1 000 live births in 2014. The decline in IMR points to an improvement in the general health and living standards of the population.*”

²⁰⁹ National Health Insurance In South Africa: Policy Paper, page 7.

²¹⁰ *The Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC), paragraph 44

²¹¹ *The Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC), paragraph 44.

In the case of *Mazibuko v City of Johannesburg*²¹² the Constitutional Court stated the need to have government measures regularly reviewed, adding that a policy cast in stone and never revisited is unlikely to be a policy that will result in the progressive realisation of socio-economic rights. In my view both the National Health Insurance Policy Paper and South Africa's Draft National Policy on Intellectual Property (IP) represent a review of the National Drug Policy. The Competition Commission's market inquiry on the private health sector also represents such a review. However, it seems unlikely that these reviews will pass the test because they are irregular and unscheduled. The Constitution requires that government must deliberately set scheduled review programmes. These reviews were prompted by apparent problems and lack of universal coverage in particular. However, if there were scheduled regular reviews, these problems would have been detected and forestalled before they could become visible.²¹³

The conceptual content of the policy and legislative measures which the South African government has in place to decrease the price of drugs and make them affordable are clearly well thought out. They hit all the right notes, but a discord occurs in implementation. Take for instance the provisions of the Patents Act which allow for compulsory licensing, which have never been used by government in its effort to extend coverage. This is also caused by what can be referred to as fragmentation and intervening interests.²¹⁴ Since the Patents Act is administered by the DTI it follows that it affects the interest of the Department of Health and possibly other government departments as well. So whilst the Department of Health might want to push for compulsory licensing, the DTI will be worried about the implications of such a measure for in the economy. We have noted that compulsory licensing is allowed by TRIPS under certain circumstances but the

²¹² 2010 (4) SA 1 (CC).

²¹³ Paragraph 3 of the Competition Commission Market Inquiry outlines the problems which are the rationale for the market inquiry: Government Gazette No. 37062.

²¹⁴ The Industrial Policy Action Plan: Economic Sectors and Employment Cluster; IPAP 2014/15-2016/17 states: "It is of paramount importance that the policies of the relevant departments - those of the National Health Department (DoH) and the DTI - - are fully harmonised and coordinated to transform this growing economic burden into an opportunity for the SA economy."

USA government is opposed to the relaxation of patents rights offered under TRIPS and so this opposition will definitely worry the DTI.

Instead of compulsory licensing, government has resorted to encouraging the use of generic medicines. However, as noted above, there is little to choose from between originator products and generics in terms of price. In the case of *Cipla and Others v Aventis*²¹⁵ the Supreme Court of Appeal granted an interdict in favour of the originator company against the generic manufacturer, noting that the difference in cost was marginal (barely noticeable).

The two measures (Draft National Policy on Intellectual Property and the National Health Insurance Policy) aimed at decreasing the price of drugs are nowhere close to being a reality. While publication of the South African Draft National Policy on Intellectual Property (IP) must be welcomed, the crucial question is whether government will have the courage to see it through, because it has back-tracked on the question of compulsory licensing before.

On the other hand the National Health Insurance Policy is still at the pilot stage. On 27 March 2015 a newspaper report announced that the National Health Insurance pilot programme had run into serious difficulties, some of which were “insurmountable”.²¹⁶ It was reported that due to a change in South Africa’s economic outlook, the Department of Finance was reluctant or unable to invest more money into the National Health Insurance Policy. It was further stated that for lack of incentives to back up their endeavours, government has failed to convince practitioners working in the private sector to pitch in with the public sector. On 21 April 2015 the Minister of Health told listeners to Gauteng Radio Station 702 that the article was malicious. He admitted that some months earlier

²¹⁵ Case No. 139/2012, paragraphs 55-61.

²¹⁶ Business Day (2015-03-227), www.bdlive.co.za/opion/editorials/2015/03/27editorial-ailing-system-doms-nhi

the article would have been correct, but that the situation had changed and the Department of Finance was on board. He indicated that the journalist who wrote the story was provided with current information and he was surprised that the story was still published in its format.

Part of the problem is that the pharmaceutical companies seem to operate on the premise that they owe society nothing and that it is incumbent on government and private funders to pay them whatever they demand for their products. Subjecting prices of drugs to so-called market forces in a market dominated by patents protection and therefore special monopolies, is unconstitutional. The Bill of Rights is equally binding on natural and private persons alike, which means that drug pricing cannot depend only on overheads and the biggest profit that can be extracted from consumers; rather, maximising profit must be qualified by the fact that the product in question is a right and not a luxury. This is clearly a problem because the pharmaceutical companies are still at liberty to set their SEPs.

In making a point for regulation of medicines Vawda and Baker regard medicines as “public goods” which should not be left to the mercy of market forces and according to them; “‘public good’ are goods that are essentially social in character, even though (like medicines) they may be intended for private consumption.”²¹⁷ Gray and Matsebula also state that “medicines are not ordinary articles of trade. Specifically, their demand and supply characteristics do not follow classic market principles.”²¹⁸ According to Gray and Matsebula market forces rarely reflect true social costs and benefits, and cannot meet social objectives such as equity. Gray and Matsebula prefer to look at medicines as “meritorious goods” which must be regulated by government.²¹⁹

Whatever the case, it is clear that South Africa is still far from achieving universal health coverage. The poor, and in particular those who are in need of health care, still cannot

²¹⁷ Vawda Y & Bakker B “Achieving Social Justice in the Human Rights / Intellectual Property Debate: Realising the Goal of Access to Medicines” AHRLJ 2013 (13) 55.

²¹⁸ Gray A & Matsebula T “Drug Pricing” SAHR 2000 201

²¹⁹ Gray A & Matsebula T “Drug Pricing” SAHR 2000 201

afford drugs. Consequently, government measures aimed at reducing prices of much needed drugs are at the moment unreasonable and unconstitutional.

4.3. Conclusion

Factors to which high drug costs are ascribed internationally were dealt with in chapter 1, namely: duties; taxes; mark-ups; distribution costs and dispensing fees; patents regulation; level of competition and the lack of social insurance. The South African National Drug Policy recognises and endeavours to address these issues.

The DTI appears to be the main driver in most of the measures which are supposed to turn around the pharmaceutical sector. The tax incentive scheme, SIP is managed by the DTi and administered by SARS. These tax incentives are placed at the disposal of industry players to encourage investment in the local manufacturing sector. The SIP is critically flawed in that there is no obligation on the recipient to pass the concession on to consumers in the form of low drug prices, nor is there any research initiative to discover how SIP has affected the prices of locally manufactured drugs. The DTI believes that encouraging local manufacturing of drugs will reduce the cost of procurement because it will reduce the primary and secondary taxes paid by domestic manufacturers but it lacks detail on how such tax breaks will translate into lower drug prices, particularly because manufacturers are free to set their SEP.

Customs seems to be a difficult area to manage. The DTI would definitely want to raise custom duties for imports in order to protect and grow local manufactures, but if it does, it risks becoming protectionist and breaking WTO trade rules and, most crucially, jeopardising security of supply, because South African manufacturers depend on the international suppliers for inputs, and they only supply a limited requirement of the total drugs consumed in South Africa. SEP is meant to address distribution costs and

dispensing fees, and as we have seen, it has resulted in lower drug prices. The Patents Act has not been used positively in the procurement of drugs. The Competition Act whilst it theoretically provides for possible mechanism to reduce the price of drugs it has also not provided a legal precedent. The research acknowledges that the measures taken by government to achieve low prices for medicines depict strong conceptual content but their implementation have not produced the desired results.

Even though the Constitution states that it is the supreme law of the Republic, implying that the curtain between private and public law has fallen because all law is required to comply with the Constitution Vawda and Baker make an interesting point. They observe that intellectual property law has largely remained private, only emphasising the rights of patents holders and makes nothing of the right of the public.²²⁰

It remains to be seen whether the NHI and the New National Policy on Intellectual Property will be the final panacea. On 10 December 2015, the minister of health release the NHI White Papers (“the NHI White Paper”). The NHI White paper proposes explains that in order to expand access to pharmaceuticals and to ensure equitable access to medicines, medicines will be procured from accredited and contracted retail pharmacies. The accredited and contracted pharmacies will in turn be able to order stock from the nationally agreed pharmaceutical contracts and will be required to sell the medicines at subsidized prices.

On 13 January 2016 the Times Live reported that a medical lawyer, Neil Kirby has cautioned that the NHI is unconstitutional because it requires all citizens to contribute to a common pool through taxes and takes away the role played by private medical aids.

²²⁰ Vawda Y & Bakker B “Achieving Social Justice in the Human Rights / Intellectual Property Debate: Realising the Goal of Access to Medicines” AHRLJ 2013 (13) 55.

Reportedly, he argued that the NHI at its current form violates citizen's freedom of association.²²¹

On 20 January 2016 the Mail and Guardian reported that the Free Market Foundation was accusing the Minister of Health of using the Competition Commission Market Inquiry of as a tool to regulate private health care prices so that he can be able to implement the NHI.²²² On 21 January 2016 the Mail and Guardian again reported that the Free Market Foundation has complained that NHI is going to collapse the economy. The Free Market Foundation, according to the Mail and Guardian stated that the NHI will require R 367.4 billion more than the country's entire income tax collection of R 251.9 billion for 2014.²²³ The Minister of Health in his response stated that the Free Market Foundation was just trying to protect the interest of business and ignoring the interest of people.²²⁴

Judging from this criticism we can conclude that the NHI will end up in courts. At this moment, government has failed to reduce the price of drugs to the extent of allowing the poor and vulnerable access to much needed drugs and therefore all the measure do not pass muster.

CHAPTER 5

RECOMMENDATIONS

²²¹ Times Live (2016-01-13), www.timeslive.co.za/2016/01/13NHI-unconstitutional-says-medical-lawyer, accessed on 23 January 2016.

²²² Mail and Guardian (2016-01-20), www.mg.co.za/article/2016-01-20-motsoaledi-accused-of-seeking-justification-to-control-prices, accessed on 23 January 2016.

²²³ Mail and Guardian (2016-01-21), www.mg.co.za/article/2016-01-21-motsoaledi-strikes-back-at-nhi-critics, accessed on 23 January 2016.

²²⁴ Mail and Guardian (2016-01-21), www.mg.co.za/article/2016-01-21-motsoaledi-strikes-back-at-nhi-critics, accessed on 23 January 2016.

The NHI White Paper recognises that expanding population coverage, service coverage and cost coverage will not be possible if the public and private health sectors are left as they are. The NHI White Paper recognises that there will be a need for legislative change, rearrangement of health functions, responsibilities and relationships within the three spheres of government. The NHI Green and White Papers are noble ideas but it is doubtful that the application thereof will be different from previous and current policies and/or legislations which were aimed at achieving universal coverage. Both the NHI Green and White Papers are overladen with ideas and this will lead to the implosion of the NHI.

At this moment the African National Congress (“ANC”) does not have the required parliamentary two third majority in order to effect amendment to the Constitution²²⁵ and there’s no guarantee that it will ever attain the right numbers to be able to amend the Constitution. In the past when government tried to introduced legislative measures to regulate prices it was challenged in courts and it backtracked hence the price of medicine is not regulated at wholesale level. It therefore appears that the NHI is a noble attempt to attain many goals at ones and should the government be bogged down by one goal, the whole project will be at risk of failing.

Pacing will be very important if government is to be able to reduce the cost of medication in South Africa. Lumping the goal to reduce prices for medicines with other goals will only serve to make the project costly, prohibitive and susceptible to legal challenges. Government must also stay away from cost subsidization. This simple means government is trying to appease pharmaceutical manufacturers but the down side of it is that it increases the cost of medication. Subsidization does not make medicine affordable, it makes it costly because it is tax payers who fund it. Subsidization creates a heavy burden on the few that are employed and earning a taxable income.

²²⁵ Section 74 of the Constitution.

Government simply has to come up with a reasonable method/formula to determine prices at a wholesale level. Indeed meaningful consultation will be required on the part of government. This can be achieved by using experts who will take views from manufacturers of drugs, consumers and all interested parties. The pricing formula should be used to determine reasonable profits on medicines at wholesale level. This means that the price at which manufacturers sell to the wholesalers must also be regulated. As Chang puts it; “[t]he free market doesn’t exist. Every market has some rules and boundaries that restrict freedom of choice.”²²⁶

It is therefore recommended that the NHI White Paper must be treated as a diagnostic document and not as a project to be delivered at once. Rather all the objectives should individually be treated as projects on their own. This will ensure that the failure of one objective does not affect the progress of the other and will render the achievement of all objectives less susceptible to legal challenges.

²²⁶ Ha-Joon Chang, (2010) page 1.

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