

Submission to the South African Human Rights Commission enquiry into access to health care services

17 April 2007

1. Introduction

The AIDS Law Project (ALP), the National Education, Health and Allied Workers Union (NEHAWU) and the Treatment Action Campaign (TAC) welcome the decision of the South African Human Rights Commission (SAHRC) to hold a public enquiry into health care in South Africa.¹ We believe this is both necessary and fully in keeping with the SAHRC's constitutional and statutory responsibilities. However, we are concerned about the manner in which this

¹ This submission has been prepared by the ALP with input from NEHAWU and TAC. Within 30 days, the TAC will make its own submission explaining how the state is not meeting its duty to take reasonable measures to make medicines available that prolong life or improve its quality. The TAC submission will contain the following:

- It will recommend steps that can be taken to strengthen the state institutions tasked with making safe, effective, quality medicines accessible and stop the marketing and selling of unproven medicines.
- It will describe medical technologies for HIV and TB that either already exist or can be developed easily. All are essential, in that if successfully implemented, the quality and length of life for many people will be improved. With suitable political will, most of these interventions can be introduced into the public health system by mid-2008.
- It will also describe some examples of unregistered medicines being marketed and sold as treatments for AIDS and the failure of the state to stop these practices.

In particular, the TAC submission also describe how the state has failed to enforce the Medicines and Related Substances Act 101 of 1965 by not taking action against unethical medicine sellers who market unproven remedies for the treatment of HIV. It will describe the examples of Matthias Rath, Zebulon Gwala, Steven Leivers and Tine van der Maas.

In addition, the TAC submission will describe how government is not delivering key technologies, for example:

- **Tenofovir**, an antiretroviral (ARV) medicine with fewer side-effects than one currently used in the public health system and that was registered by the Food and Drug Administration in the United States in 2001 but is still not registered by the Medicines Control Council in South Africa as of April 2007.
- **Fluconazole**, an antifungal medicine used to treat oesophageal thrush and cryptococcal meningitis, two AIDS-defining opportunistic infections. Fluconazole is donated free to the public health system but is still only available in less than 15% of health facilities.
- **More sophisticated regimens for the prevention of mother-to-child transmission of HIV (MTCT) than the single-dose nevirapine regimen used in eight of nine provinces.** The Western Cape government has replaced the single-dose nevirapine regimen with a more effective one using both nevirapine and zidovudine (AZT). Consequently, child mortality has dropped. Yet no other province implements this simple, cost-effective regimen.

process has been undertaken thus far. In particular, there seems to have been very little effort to advertise the enquiry and invite submissions, as well as to ensure that interested parties are given sufficient notice to prepare appropriately. Many important stakeholders, including largely unorganized users of the public health system, are still unaware of the enquiry.

We therefore recommend that the SAHRC extend the deadline for the submission of written input, publicise the hearings widely (for example, by making use of local newspapers, community radio and other relevant media) and hold public hearings at venues across the country that are accessible to ordinary members of the public.

In addition, we strongly urge the SAHRC –

- to subpoena key government officials to testify at the enquiry (we make recommendations in this regard later in this submission); and
- as part of its report on the hearings, to include an action plan that sets out how the SAHRC will actively follow up whatever recommendations it may make – this is essential if the SAHRC is committed to avoid raising public expectations in a process that turns out to be a mere venting without remedies.

This submission begins by considering the following five issues that collectively paint a disturbing picture of the state of our health:

- Increases in infant and adult mortality;
- Impact of HIV-related mortality and morbidity on the standard of care in the public health system;
- The failure properly to implement the Cabinet's 2003 Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa ("the Operational Plan") and prevent HIV-related deaths;

- The failure of HIV prevention; and
- Undermining legal systems to ensure the safety of medicines.

Thereafter, it focuses on the following key aspects of health service planning and delivery:

- Defining needs: an essential package of health care services;
- Staffing the health system;
- Ensuring access to medicines;
- Governance issues: disrespect for the rule of law and the Constitution;
and
- Regulating the health sector.

The submission concludes with a summary of our recommendations, including our proposals regarding the ongoing constitutionally-required role of the SAHRC in holding the state to account for discharging its obligations in respect of the right to have access to health care services.

In making these submissions we are mindful of the significant shift in government's approach to HIV/AIDS, most vividly expressed in the development of the *National HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011* ("the NSP") under the leadership of Deputy President Phumzile Mlambo-Ngcuka, Deputy Minister of Health Nozizwe Madlala-Routledge and Dr Nomonde Xundu, chief director of HIV and AIDS, TB and STIs in the national Department of Health ("the DoH"). Whilst welcomed and recognised, this progress does not detract from the analysis and criticism of the DoH set out in this submission. In our view, the progress achieved in respect of HIV/AIDS should similarly be expanded to all other aspects of health care policy and service delivery in South Africa.

2. Executive Summary

This submission argues that there is a growing crisis of disease and ill health in

South Africa that not only undermines the quality of life of millions of individuals, but also crucial programmes aimed at the reconstruction and development of the country. Much of this crisis could have been avoided. It results, in large part, from the failure of government to recognize the link between fundamental rights to dignity, equality and autonomy and the state's constitutional obligations in respect of the right to have access to health care services.²

In addition, government has on several key occasions failed to consider the implications of its economic policy for the right to health. The starkest example of this was the Growth, Employment and Redistribution (GEAR) strategy, which, at a critical point, led to a period of decreasing real per capita health expenditure. According to the DoH itself, real per capita expenditure declined from R928 in 1997/98 to R894 in 2000/2001 (in 2002 prices).³ We intend to lead evidence during the public hearings on what has actually occurred from this period.⁴

This decrease caused significant damage to the DoH's capacity to deliver quality health care. It also increased the dependence of those with some money on private health care, adding to inequalities. These errors are now being compounded: by a policy of contracting-in private sector "expertise" to manage aspects of the public sector, as well as moves to shift low-income earners from the public to the private health sectors. These measures exacerbate rather than address the underlying problems.

The submission argues that rights violations lie at the heart of the problem – and

² These issues are explored more fully in Adila Hassim, Mark Heywood and Jonathan Berger (eds.), *Health & Democracy: a guide to human rights, health law and policy in post-apartheid South Africa* (SiberInk: Cape Town, 2007), in particular at chapters 1 (A background to health law and human rights in South Africa), 2 (The Constitution and public health policy) and 6 (The private health care sector). A hard copy of *Health & Democracy* (which is available in electronic format <http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=351>) will be made available.

³ DoH, *Essential Health Care for All South Africans: an investigation into the adequacy of public health financing and the equity of provincial health resource distribution* (September 2003). A copy of this report is available from the ALP.

⁴ Concerns will also be raised regarding the public representation of the health budget allocations, which are misrepresented to create the impression that there are improvements.

that recognition and the discharging of the state's positive duties in respect of health care access are central to the solution. To illustrate this argument the submission:

- briefly summarises some of the empirical information that has been gathered about health in South Africa;
- argues that an analysis of the relevant data, statistics, laws and court decisions will lead the SAHRC to concluding that defining the essential package of health services to all people in South Africa are – by law – entitled is both long overdue and urgent;
- concludes that only by engaging in such a process would it be possible to cost the health service accurately;
- argues that government has consistently and deliberately avoided developing and implementing a methodology for calculating the needs of the public health system – and that consequently public health care is chronically under-funded, resulting in government's own policy framework and major objectives for health being undermined;
- unpacks the implications of the right of access to medicines – an integral aspect of the right to have access to health care services – for the review, development and implementation of the National Drug Policy and as an example of the level of national government planning, stewardship and service delivery demanded by the Constitution;
- draws attention to the poor governance of our health system and recommends that a range of health officials be subpoenaed by the SAHRC to account publicly at its hearings; and
- considers how the health sector should be regulated appropriately.

3. The state of our health

In the analysis below, we concentrate much of our focus on HIV/AIDS. This is because the epidemic is an exceptional political, social, economic and health crisis and challenge that requires everyone to act under the bold leadership of

government. In addition, the focus helps to draw attention to a range of issues that remain relevant to HIV/AIDS and all other public health challenges, including the need for:

- appropriately planning to deal with emergency, short-, medium- and long-term needs;
- information sharing and collaboration between different government departments,⁵ and between government, civil society, organised labour and business;
- evidence- and needs-based policy planning and implementation; and
- prioritising major health challenges and the needs of the poor, who are particularly vulnerable.

In focusing on the epidemic, however, we caution against viewing the state's response to HIV/AIDS – particularly during the period May 1999 to September 2006 – as an aberration. Such an approach would lead to the unjustifiable conclusion that the adoption and proper implementation of the NSP would – in and of itself – ensure that all the ills of the health system and DoH were remedied. This is clearly not possible.

Instead, we view the state's response to HIV/AIDS as indicative of government's broader failures in respect of health service planning and delivery. The evidence shows that there has been a marked deterioration in many other areas of the public health system, demonstrating a general failure by the government to prioritise and manage health care in South Africa. This is despite our countries' high level participation in the World Health Organization's Commission into Macroeconomics and Health, which was followed by a failure to absorb, understand or implement the Commission's findings and recommendations.⁶

⁵ These include, but are not limited to, the Treasury and the departments of correctional services, defence, education, social development and trade & industry.

⁶ We draw the SAHRC's attention to the report, available at www.who.int/marcohealth/en/en.

3.1 Increases in infant and adult mortality

Since 1999 there has been a continual increase in HIV/AIDS related deaths. This has been demonstrated by five separate government research reports.⁷ These reports reveal as follows:

- Since 2000, the majority of adults die in their 20s, 30s and 40s instead of in their 60s or 70s.
- Today, more infants and children under five die than at any other time in recorded South African history.
- The number of children infected through mother-to-child HIV transmission (MTCT) was estimated to be over 60,000 in 2005.⁸ These high numbers persist despite a 2002 Constitutional Court order to the government to implement a national programme to prevent MTCT. Currently this programme is unmanaged, unmonitored and run in accordance with protocols that are no longer in accordance with World Health Organization guidelines.
- The maternal death rate almost doubled between 1997 and 2004.^{9 10}

Until the recent interventions of the Deputy President and the Deputy Minister of Health following the Toronto International AIDS Conference in August 2006, the crisis of AIDS had not resulted in the development or implementation of a clear action plan by the Health Ministry aimed at mitigating the crisis of HIV-related

⁷ These five studies are by statutory bodies:

- *The Impact of HIV/AIDS on Adult Mortality in South Africa*, published in 2001 by the Medical Research Council (MRC, 2001),
- *Causes of death in South Africa 1997-2001: Advance release of recorded causes of death* published by Statistics South Africa in 2002 (Stats SA, 2002),
- *Mortality and causes of death in South Africa, 1997-2003* published by Statistics South Africa in 2005, and
- *Mortality and causes of death in South Africa: Findings from death notification 2003, 2004*, published by Statistics South Africa in 2006.
- Adult mortality (age 15-64) based on death notification data in South Africa: 1997-2004, published by Statistics South Africa in 2006.

⁸ ASSA 2003 model published by the Actuarial Society of South Africa.

⁹ Adult mortality (age 15-64) based on death notification data in South Africa: 1997-2004, published by Statistics South Africa in 2006.

¹⁰ Report of Confidential Committee of Inquiry

mortality. Instead, the Ministry has at times been directly implicated in convincing desperate people living with HIV/AIDS not to take antiretroviral (ARV) medicines but to take untested medicines that are marketed and sold in breach of the Medicines Act.

3.2 Impact of HIV-related mortality and morbidity on the standard of care in the public health system

In November 2000, the Health Minister received a report that demonstrated the impact HIV would have on the health sector. The report said that there would be an increase to more than 1 million HIV-related hospital admissions and 15 million HIV-related bed days in public health facilities by 2006.¹¹ But instead of preparing to mitigate this impact, the Ministry was actively engaged in denying the benefits of registered ARV medicines (covering a period from 2000 to late 2006), creating confusion and uncertainty about medical care. This has directly contributed to the burden of ill-health on individuals, families and the health system.

The HIV crisis cannot be managed without a plan – dealing with emergency, short-, medium- and long-term needs – to staff the public health system. However, in the last few years the shortage of health workers – as the following statistics demonstrate – has grown substantially worse:¹²

- The number of enrolled nurses has dropped from 60/100 000 public sector users in 2000 to 52/100 000 public sector users in 2005.
- The number of professional nurses has dropped from 120/100 000 public sector users in 2000 to 109/100 000 public sector users in 2005.
- Nursing assistants have dropped from 81/100 000 public sector users in 2000 to 78/100 000 public sector users in 2005.

¹¹ *Health sector impacts of HIV/AIDS: Key issues for planning* by Martin Hensher (Directorate: Health Financing and Economics). Presented to SANAC in 2000.

¹² Health Systems Trust, *South African Health Review 2005*

However, whilst public health worker per patient ratios decline, the demand on public health facilities is increasing. For example, the percentage of the population with medical scheme coverage dropped from 16.2% in 1999 to 14.9% in 2003. From 1999/2000 to 2002/2003 the ratio of private spending per patient compared to public spending per patient has increased.¹³ At the same time, there has been no attempt to determine minimum staffing standards and to plan for their achievement. Simply put, the declines in ratios were not a function of policy, but instead appear largely to be symptomatic of the absence of any reasonable planning.

3.3 The failure properly to implement the Cabinet's Operational Plan and prevent HIV-related deaths

The most plausible estimate is that at least 700 000 people with HIV need ARV treatment now.¹⁴ The Cabinet-approved Operational Plan itself committed the state in 2003 to placing approximately 645 740 people on ARV treatment in the public sector by the end of the 2006/7 financial year, being 31 March 2007. But, according to the DoH, approximately 250,000 people had been initiated on ARV treatment in the public health sector by this time – less than 40% of the target.¹⁵

South Africa is ranked only 11th in Africa for the proportion of people on ARV treatment who require it.¹⁶ There are long waiting lists for ARV treatment at many of the facilities that provide it. Yet the Ministry has consistently refused to address these bottlenecks. To date, the DoH has maintained unjustifiable and unreasonable “accreditation” criteria, with the accreditation process being managed by a small team from the DoH tasked with assessing all potential treatment sites across the length and breadth of a country with more than 4 000 public health facilities. Instead of the accreditation process being used to

¹³ Ibid.

¹⁴ Actuarial Society of South Africa, ASSA 2003 model

¹⁵ Unfortunately, neither the DoH nor civil society is able to verify this figure because of poor monitoring and evaluation systems.

¹⁶ Based on *Coverage Survey 2005* estimate on page 557 in *2006 Report on the Global AIDS epidemic* published by UNAIDS. South Africa is ranked 16th on 3 by 5 December 2005 report.

strengthen health facilities, as was its original intention, it is being used to deny the provision of lifesaving medicines. The process artificially limits access to ARV treatment and places undue stress on “accredited” hospitals.

The Operational Plan recognises that its implementation is dependant – to a significant extent – on the availability of a sufficient number of appropriately trained health care providers. Yet the DoH’s Human Resources for Health Plan (“the HRH plan”), which is discussed in greater detail below, is silent on this issue. In other words, the DoH’s general human resource planning happens in isolation from HIV planning. In addition, the HRH plan makes no mention whatsoever of the impact of HIV/AIDS on the health workforce.

Finally, although much has been said about nutrition, there is no plan in place to address food insecurity for all people who need it, including people living with HIV/AIDS. Instead, there are serious inadequacies in the state’s nutritional programmes.¹⁷ In this respect we draw the SAHRC’s attention to the fact that section 27 of the Constitution, which recognises a right of access to health care, also recognises a right to have access to “sufficient food”. In respect of this right, government is constitutionally obliged to develop and implement a reasonable plan in accordance with the guidance provided by the Constitutional Court in its *Grootboom* decision.

3.4 The failure of HIV prevention programmes

The Cabinet statement of 17 April 2002 and many subsequent statements emphasised that prevention is the key aspect of government’s HIV programme. Yet despite government having invested significant financial resources in HIV prevention, systemic and political failures have undermined prevention programmes. Consequently there has been an almost uninterrupted rise in HIV prevalence for 17 years, notwithstanding the high rates of AIDS-related mortality:

¹⁷ Available at <http://www.tac.org.za/Documents/JCSMF/4thJCSMFmeeting.pdf>

- On average over 1000 people are infected with HIV in South Africa every day.¹⁸
- Prevalence among pregnant women attending antenatal clinics continues to rise. Prevalence amongst pregnant women under 20 – the age group at which most state-sponsored prevention efforts are aimed – has been at 16% with statistically insignificant fluctuations for several years.
- The decline in the growth rate of prevalence is likely primarily due to deaths of people with HIV, rather than a decline in new HIV cases.

The recent commitments to accelerated and improved HIV prevention contained in the NSP are important, but need great political will if they are to be implemented. For example, although there is a national programme to make life-skills education – including sex education – available in schools, the Minister of Education has undermined this plan by opposing access to condoms in schools. Generally, while condom distribution has improved, it is still insufficient. No effort has been made by the state to compel the patent-holder of the female condom to reduce the price.

Similarly, there is also no constitutionally defensible national plan to reduce violence against women, which has been described by UNAIDS as a key factor driving the HIV epidemic. Many health facilities do not provide post-exposure prophylaxis (PEP) services. The TAC continues to receive reports from health care workers and survivors of rape who have been unable to access PEP services in the public health system timeously.

3.5 Undermining legal systems that ensure the safety of medicines

In recent years, the Ministry of Health has allowed unethical experimentation on black African people, violating international conventions, common law, statutory and constitutional provisions. This has fostered an environment in which unproven ‘quack’ remedies are now advertised and sold with impunity. Yet

¹⁸ ASSA 2003

despite being presented with clear evidence that the health of the public has been placed at risk, the DoH has refused to act.

In particular, the TAC has put evidence before the courts of the state's failure to take appropriate action – as contemplated by the medicines regulatory framework – against Matthias Rath, a discredited vitamin salesman with court rulings, advertising authority rulings and regulatory authority warnings against him for unethical marketing in several countries including South Africa. Instead of investigating the allegations, which include unlawful marketing and selling of unregistered medicines and conducting clinical trials without ethical committee approval, the DoH has inappropriately supported Rath's activities.

In addition, the DoH has issued two statements in support of Ubhejane, an untested and unregistered product that is marketed and sold as a medicine for the treatment of AIDS. Despite doctors' reports of deaths and illness due to patients taking Ubhejane and Matthias Rath's products instead of ARV treatment, the DoH remains unwilling to act.¹⁹

4. Key aspects of health service planning and delivery

While significant time and resources have been allocated to the development of a range of health care policies and laws since 1994, the gap between these policies and laws on the one hand and actual implementation – the delivery of health care services – on the other has widened. In addition, the delays in implementation and ongoing political and scientific developments regarding many aspects of health care domestically and internationally mean that many important parts of the regulatory framework require urgent review and possible amendment.

¹⁹ Officials from the Ministry, including senior officials, have also made numerous statements promoting various food products – including garlic, beetroot, lemons, spinach and African potatoes – as treatments for AIDS. This is in violation of the DoH's own guidelines on nutrition for people living with HIV/AIDS.

4.1 Defining needs: an essential package of health care services

One of the objects of the National Health Act 61 of 2003 is to provide “in an equitable manner the population of the Republic of South Africa with the best possible health services that available resources can afford.” According to section 3(1)(d) of the Act, the Minister of Health must:

“Within the limits of available resources ... ensure the provision of such essential health care services, which must at least include primary health care services, to the population ... as may be prescribed after consultation with the National Health Council.”

Primary health care services are defined by the Act as “such health care services as may be prescribed by the Minister”, with essential health services being defined as “those health services prescribed by the Minister to be essential health services after consultation with the National Health Council”. In turn, health services are defined to include:

- “health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution”;
- “basic nutrition and basic health care services contemplated in section 28(l)(c) 25 of the Constitution”;
- “medical treatment contemplated in section 35(2)(e) of the Constitution”;
- and
- “municipal health services”.

Unfortunately, two years after the bringing the Act into effect, these definitions remain elusive, with the Minister having failed to define both primary and essential health services.²⁰ This means that a baseline for the right to health still does not exist, that it is impossible to cost the health service and thereby

²⁰ Numerous other regulations are still required to give full effect to the statutory framework provided by the National Health Act.

determine objectively what can be afforded.

In our view, three steps are essential and urgent to unblock this problem.²¹

1. Immediately establishing an expert process accurately to determine the health needs of people living in South Africa, to be based – amongst other things – on population statistics and the burden of disease, including the special needs created by diseases such as HIV infection and TB;
2. Expanding the expert process to consider – on the basis of internationally accepted norms, standards and staffing ratios – the staffing requirements if the needs are to be met; and
3. Concluding the expert process by costing these needs in collaboration with the Treasury.

It is important for the SAHRC to be aware that a precedent for such a process exists in the manner in which the NSP was finalised. This plan was developed in close consultation with an expert committee that determined the key components of the plan and the feasibility of its targets. Thereafter, key components were costed. It is significant to note that the costing exercise found that the resources needed by the NSP over five years (R45 bn) are far greater than the R14bn that has been allocated by the Treasury in the Medium Term Expenditure Framework. It is likely that a similar exercise for the entire health system would determine costs in excess of the current budget. This in turn would lend urgency to measures available to the state to reduce the price of medicines (see 4.3 below) and to challenge costs and inefficiencies in South Africa's private health sector.

4.2. Staffing the health system

Sufficient essential health care workers (including nurses, doctors, dentists, dieticians, cleaners, security personnel, managers etc) are needed if the state is

²¹ See also Adila Hassim, "Civil society submission: basic package of health care services", Health Charter Task Team (17 March 2006), attached hereto as Annexure ALP1.

to discharge its legal duty to provide an essential package of health care services. However, as we have already pointed out, there is a severe shortage of health care workers serving the public health sector. There is also a crisis of morale due to the combination of poor working conditions, safety concerns, low salaries and the HIV/AIDS epidemic. This crisis is made worse by the scapegoating of front line workers, particularly nurses, who are blamed by the public and media for the crisis.

The Constitution places a positive duty on government to develop and implement a reasonable human resources for health plan, in accordance with the guidelines as set out by the Constitutional Court in *Grootboom*. Following a flawed process of “consultation”, the Health Ministry launched its HRH plan in April 2006. In our view, this plan is wholly inadequate because:

- it fails to provide an accurate assessment of the human resource needs of the health system. This critical issue is left for further research beyond the HRH plan. We do not believe that there can be rational planning for HRH in the absence of data as to the needs and current capacity of the health system as a whole;
- It appears to have been drafted in a vacuum as there is no assessment (or an appreciation that there needs to be an assessment) regarding the health needs of the population. For example, there is no recognition in the plan of the increased demand for health services as a result of HIV/AIDS. Nor is there any recognition of the increased burden on health care workers as a result of the epidemic. Certainly, the implementation of the NSP will require a serious and urgent response from the DoH with regard to such issues as increasing staff ratios, improving conditions of service, and reviewing scopes of practice;

- There appears to have been no synergy between the process of drafting the plan and other health processes, such as draft health legislation²² and the Health Charter process; and
- It fails to provide any concrete recommendations for addressing specific HRH challenges by, for example, setting benchmarks, targets and indicators which are measurable.

As a result, even though the National Budget Review 2007 announced that 30 000 more health care workers would be employed over the next three years, there is no evidence as to how this correlates to the current need. If it is assumed that the population served by the public sector were to increase by 2% per annum, new staff needed would amount to 36 000. The Budget Review therefore proposes to drop the current implicit staffing norms.²³

In the result, we strongly recommend that the SAHRC:

- analyse the plan in the light of our concerns, as expressed above and as set out in the joint ALP/TAC submission on the DoH's "A Strategic Framework for the Human Resources for Health Plan: Draft for Discussion" (14 September 2005);²⁴
- subpoena Dr MP Mahlathi (Deputy Director General: Human Resources) to explain why the plan fails to comply with the dictates of the Constitution; and
- subpoena key officials from the Treasury to explain their overall allocation methodology and why the health budget is not permitted to increase.

²² We refer to the ALP submission on the Nursing Bill [B26-2005] (10 October 2005), available at <http://dedi20a.yourserver.co.za/alp/images/upload/Nursing%20Bill%20submission%20final.doc>, and the ALP submission on the Health Professions Amendment Bill [B10-2006] (21 July 2006), available at <http://dedi20a.yourserver.co.za/alp/images/upload/ALPHealthProfessions.doc>.

²³ We also don't know what category of health care workers will be prioritised for recruitment.

²⁴ A copy of this submission is attached as Annexure ALP2.

4.3. Access to Medicines

Despite assertions to the contrary, the DoH has largely failed to give full and meaningful effect to the National Drug Policy of 1996. In our view, access to medicines – an integral part of the right to have access to health care services – is dependant on:

- The availability, affordability and sustainability of supply
- Of safe and effective medicines of good quality
- Combined with access to appropriate information on the basis of which informed choices may be made.

As Annexure ALP3 to this submission shows, many of the key availability, affordability and sustainability of supply barriers have yet to be addressed in any systematic and reasonable way. Similarly, the TAC submission will show both the absence of a reasonable plan to deal with the other essential aspects of medicines aspects, as well as direct interventions by the DoH that undermine existing positive aspects of existing policy and law.

4.4. Governance issues: disrespect for the rule of law and the Constitution

The Ministry of Health has regularly displayed disrespect for the rule of law and the Constitution. Consider the following sample of judgments that have been made against the Minister:²⁵

- On 5 July 2002, the Constitutional Court ordered the DoH to implement a MTCT prevention programme, following its finding that the state's "policy was an inflexible one that denied mothers and their newborn children ... the opportunity of receiving a ... potentially lifesaving drug ... [that] could have been administered within the available resources of the state without

²⁵ In addition, the DoH has received consecutive qualified audits by the auditor-general for the last three financial years.

any known harm to mother or child.”²⁶

- On 14 December 2004, the Pretoria High Court ordered the Minister of Health to pay punitive costs in an application for certain unpublished annexures to the Operational Plan. The court found that the conduct of the Minister was unethical, unprofessional and lacked accountability.
- On 30 September 2005, the Constitutional Court declared the dispensing fee – the primary source of conflict between government and business in the latter’s challenge to the medicine pricing regulations published in terms of the Medicines and Related Substances Act 101 of 1965, stating that the Minister “*evinced a deplorable lack of respect for the SCA which is the highest court in this country in respect of all matters other than constitutional matters.*”²⁷
- In June 2006, the Durban High Court ordered the DoH and the Department of Correctional Services to provide ARV treatment to prisoners at Westville Correctional Centre “in accordance with the Operational Plan”. In August 2006, it found the state to be in contempt of court by failing to comply with an earlier interim execution order. In this regard, Justice Nicholson stated as follows:

"If the refusal to comply does not result from instruction from the first respondent, the Government of the Republic of South Africa, then the remaining respondents must be disciplined, either administratively or in an employment context, for their delinquency. If the Government of the Republic of South Africa has given such an instruction then we face a grave constitutional crisis involving a serious threat to the doctrine of the separation of powers. Should that continue the members of the judiciary will have to consider whether their oath of office requires them to continue on the bench."

²⁶ At paragraph 80

²⁷ Per Chaskalson CJ

The crisis of governance seems to have created a crisis of leadership and a lack of capacity at the most senior levels of the DoH. There is a high turnover of senior staff and key posts are vacant. This has in turn exacerbated the managerial and governance crisis. For example, the process to develop a Health Charter (which started in 2005) has reached an impasse between government and the private sector on one side and labour and civil society on the other. Similarly, the key structures of co-operative governance established in terms of the National Health Act – in particular the National Health Council and National Health Consultative Forum – are failing to ensure transparency and communication, or follow through on resolutions. A rescue plan similar to that being contemplated for the Department of Home Affairs is needed for the DoH.

4.5 Regulating the health sector

The National Health Act, other health legislation (such as the Medical Schemes Act) and non-health statutes that have an impact on health (such as the Competition Act) provide directly or indirectly for some form of regulation of the health sector. For example, the Council for Medical Schemes is a regulator with a narrow focus – “to provide regulatory supervision of private health financing through medical schemes” – that has been doing good work in its area of focus.

Similar regulation of other actors in the health sector is necessary. There are still significant gaps in the framework that, if filled, could speed up and ensure that the high cost of health care is addressed, and that quality of health care is improved. However, current legislation does not allow for the creation of other bodies that may be necessary for health sector regulation. In particular, it does not contemplate a national health sector regulator – which appears necessary to oversee the appropriate regulation of specific aspects of health care provision, such as private hospitals, laboratories and the pharmaceutical industry.

We support the establishment of an independent health regulator,²⁸ whose broad functions would include:

- Regulating the provision of health care services and facilities in the public interest;
- Working towards the realization of section 27 of the Constitution by promoting universal access to health care services;
- Ensuring competition in the manufacture and supply of medicines, medical devices and other essential health products;
- Promoting the interests of users of health care services; and
- Ensuring that the objects of national legislation are met.

In our view, the regulator should be independent and subject only to the Constitution and the law. It should be impartial and perform its functions without fear, favour or prejudice. In particular (as is the case in respect of the Independent Communications Authority of South Africa (ICASA)), it must function without any political or commercial interference.

5. Way forward

In addition to the various substantive recommendations made throughout this submission, we would like to expand on three process issues that we have already mentioned.

First, the SAHRC needs to create the space for further detailed submissions from all interested parties, including in particular frontline health care workers themselves. Only by listening to those with direct experience of the day-to-day challenges will the SAHRC be in a position properly to evaluate the impact of policies choices and executive actions on health service delivery.

²⁸ Additionally, the Competition Act could be amended to expand the range of remedies available to the Competition Tribunal (over those areas of health sector regulation that fall within the ambit of the Competition Authority).

Second, key officials (including Directors-General, Deputy Directors-General, Heads of Departments and Chief Directors) from the Treasury, the DoH, provincial departments of health and the Department of Trade and Industry should be subpoenaed to give evidence on the following issues:

- Treasury
 - Financial and fiscal framework and the level of allocation;
 - Affordability of improving the resourcing of the health system;
 - Its understanding of the constitutional requirement of the progressive realization of rights; and
 - Public private partnerships (PPPs) and their impact on health service planning and delivery.
- DoH
 - Budget allocations;
 - Norms and standards (includes staffing, service provision, prioritization and processes to establish norms and standards);
 - Its understanding of the constitutional requirement of the progressive realization of rights;
 - District health system implementation;
 - Public hospitals;
 - Implementation and review of the National Drug Policy;
 - Functioning of the Medicines Control (MCC), including its capacity to perform its key functions and the level of independence from the DoH; and
 - Private sector supply-side regulation.
- Provincial health departments
 - Budget allocation problems;
 - District systems implementation;
 - Governance failures;
 - PPPs;
 - Public hospital failures;

- Norms and standards;
- Complaints processes;
- Emergency medical services.
- Department of Trade and Industry (DTI)
 - Implications of the National Drug Policy, the Operational Plan and the NSP for legislation falling under the DTI's control; and
 - Review and amendment of legislation that limits access to a sustainable supply of affordable medicines.

Finally, the enquiry into access to health care services should provide the SAHRC with a clear identification of:

- The systemic problems facing the health system;
- Shortfalls in government's response to its constitutional obligations; and
- The key strategic issues which, if not adequately addressed, will continue to undermine the health system and health service delivery.

Based on these findings, the SAHRC should develop a set of recommendations, as well as set up a monitoring and evaluation (M&E) process to assess how its recommendations are being taken forward. This M&E process could include research and reporting, as well as follow-up hearings on specific strategic issues. In addition, the SAHRC should consider establishing a more extended hearing process for either later this year or 2008. That process, which should seek to extend and deepen the analysis and findings of the current process, should result in a further report on the health system.

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