IN THE HIGH COURT OF SOUTH AFRICA

(TRANSVAAL PROVINCIAL DIVISION)

2002(4) BCLR 356 (T)
14 December 2001

CASE NO.: 21182/2001

In the matter between:

TREATMENT ACTION CAMPAIGN	**1st Applicant**
DR HAROON SALOOJEE	2nd Applicant
CHILDREN'S RIGHT CENTRE	3rd Applicant

and

MINISTER OF HEALTH	**1st Respondent**
MEC FOR HEALTH, EASTERN CAPE	2nd Respondent
MEC FOR HEALTH, FREE STATE	3rd Respondent
MEC FOR HEALTH, GAUTENG	4th Respondent
MEC FOR HEALTH, KWAZULU NATAL	5th Respondent
MEC FOR HEALTH, MPUMALANGA	6th Respondent
MEC FOR HEALTH, NORTHERN CAPE	7th Respondent
MEC FOR HEALTH, NORTHERN PROVINCE	8th Respondent
MEC FOR HEALTH, NORTH WEST	9th Respondent
MEC FOR HEALTH, WESTERN CAPE	10th Respondent

JUDGMENT

BOTHA, J:

The three applicants have instituted what can be described as a class action, by way of application, against the ten respondents. The first respondent is the minister of Health. The second to tenth respondents are the members of the executive council for Health of the nine provinces.

All ten respondents have entered an appearance to defend and filed answering affidavits. Subsequently the tenth respondent, the member of the executive council for the Western Cape, has withdrawn his opposition. No relief is claimed against him any more.

Prayers 1 and 2 concern the dispensing of Nevirapine to pregnant women with HIV who give birth in public health institutions. In prayer 1 the applicants seek a declaratory order that the respondents are obliged to make Nevirapine available to such women where it is medically indicated. In prayer 2 the applicants seek an order compelling the respondents to make Nevirapine available in such circumstances.

Prayers 3 to 8 concern relief to compel the respondents to produce and implement an effective national programme to prevent or reduce mother to child transmission (MTCT) of HIV, including the provision of voluntary counselling and testing (VCT) and, where appropriate, Nevirapine, or other appropriate medicine, as well as formula milk for feeding. Prayer 13 is a prayer for a declaratory order.

The background to the application is the grim reality that 24% of pregnant women in South Africa are HIV positive and that 70 000 children are infected each year through MTCT of HIV. It is one the most common forms of infection. It stands to reason that the victim of such a transmission is entirely innocent.

It is estimated that about 4.68 million people, or 10% of the population are HIV positive.

HIV Aids can be treated with anti-retroviral drugs such as AZT and Nevirapine.

AZT can be used in a short course for the prevention of MTCT. That involves using 300mg twice daily from the 36th week of pregnancy and 300mg every two hours during labour.

AZT was used in Khayalitsha in the Western Cape and a significant reduction of MTCT, up to 50% was recorded there since January 1999.

Nevirapine was tested in Uganda in the HIVNET012 trial. It was also tested in South Africa in the so called SAINT study.

There have been reports of side effect like skin disease and liver problems where Nevirapine is used on a long term basis.

Resistant mutations have been found after the application of Nevirapine. The evidence indicates, however, that these mutations cause no harm to the mother, and are transient.

Breast feeding can also cause MTCT of HIV. Thus the effect of the application of an anti-retroviral drug administered during labour can be undone. It does not follow, however, that a child who was born free of HIV as a result of the application of a drug like Nevirapine will be infected with HIV through breast feeding. There is a percentage who will not contract HIV through breast feeding. The risk of MTCT through breast feeding can be eliminated or reduced by formula feed.

Other aspects that are important in the reduction of MTCT are testing and counselling. Only pregnant women who have been positively tested for HIV should receive anti-retroviral drugs. Then a pregnant woman who is HIV should receive counselling with regard to her options and, should she choose the option of taking an anti-retroviral drug, she should be counselled regarding the issue of breast feeding. These aspects have cost implications in the form of remuneration for lay counsellors and the price of formula feed.

This application is closely linked to the use of the drug Nevirapine.

Nevirapine is used alone as a single oral dose of 200mg to the mother during labour and a single oral dose of 2mg/kg to the infant within 48 to 72 hours after birth or before discharge, whichever is earlier.

Nevirapine was registered in April 2001 for treatment of HIV-1 infection to reduce the risk of intrapartum transmission of HIV-1 from mother to child in pregnant women who are not taking anti-retroviral therapy at the time of labour. It was registered subject to the condition that the manufacturer continue to provide data on the performance of the drug. It was also a requirement that the patient be informed that breast feeding is counter-indicated.

During July 2000 the manufacturer of Nevirapine, Boehringer Ingelheim, made a public offer to supply Nevirapine to public health authorities in South Africa free of charge for 5 years. The respondents have not yet accepted the offer, but are negotiating the terms of its acceptance.

It appears from the papers that the cost of Nevirapine as such is negligible. Since 8 January 2001 the cost per dosage is R10-00.

The respondents have decided to make Nevirapine available for the prevention of MTCT at only a limited number of pilot sites, also called research and training centers. According to the decision there would be two pilot sites per province, therefore 18 in total. In Gauteng, for instance the

designated sites were the Natalspruit Hospital and the Kalafong Hospital. (There already was a research site at the Chris Hani Baragwanath Hospital). The decision of the respondents was apparently made at regular meetings of the respondents in a structure called Minmec, a meeting of the minister and MEC's.

These pilot sites, when operating, will serve about 10% of the population.

In Gauteng the number of research sites have been extended beyond the designated two. An MTCT prevention programme was available at the Leratong, Carletonville, Coronation and Johannesburg Hospitals by 17 October 2001 and was due to be available in November 2001 at the Sebokeng Hospital and the Garankuwa Hospital by February 2002.

On 17 July 2001 the applicant=s attorney wrote a letter to each of the respondents in which it demanded what, in essence, is claimed in this application. The first respondent replied by means of a letter dated 6 August 2001 in which she acknowledge the health problem posed by HIV/AIDS and invited the applicants to a dialogue. She referred to the problems of sero conversion as a result of breast feeding, and the need to counsel pregnant women not to breast feed and the need to provide nutritional substitutes. She concluded by referring to the cost implication of all this and stressed the fact that the State had to balance the need of the many patients dependant in its health care.

The application was launched on 21 August 2001.

The applicants annexed affidavits by the following persons to its application: ms S Mthathi, the deputy chairperson of the first applicant, dr Robin Wood, a medical specialist in the employ of the provincial administration of the Western Cape, dr Q A Karim, an epidemiologist, professor K D Bolton, a pediatrician, professor P A Cooper, a pediatrician, professor M Price, the dean of the Department of Health Sciences at the University of the Witwatersrand, dr N J N Natrass of the School of Economics of the University of Cape Town, ms CC Hardy, of the University of the Witwatersrand, ms T Mahlonoko, a nurse, ms V Matebula, a nurse, dr H Saloojee, a professor in pediatrics, who is the second applicant, ms C J Vawda, the director of the Child Rights Centre and a

number of women who testified about their experiences after having been tested positive for HIV during pregnancy.

On behalf of the first respondent affidavits by the following persons were filed: the director-general of Health, dr A Ntsaluba, dr P N Simelela, the chief director of its HIV/AIDS program, dr J B Levin, a senior statistician at the MCC and dr P C Onyabuyo, a member of the MCC.

On behalf of each of the remaining respondents an affidavit by either the head of the department of Health or someone representing him, was filed.

Replying affidavits by ms Mthathi, dr Wood, dr Cooper, dr Natrass and dr Karim were filed. Replying affidavits by the following new deponents were also filed: Dr P I Folb, a professor in pharmacology at the University of Cape Town, dr P Schoeman, a pathologist, dr M Wainberg, a professor in Microbiology and Immunology, professor H Schneider of the department of Public Health at the University of the Witwatersrand, mr C Allan, the director of the Public Service Accountability Mentor at Rhodes University, dr L Guay, a professor of Pathology and Pediatrics at the John Hopkins University, dr H Reuter, a member of the first applicant, dr S Grant, the acting medical superintendent of the Bethesda Hospital at Ubombo in Northern Kwazulu Natal and mr Budlender, the applicant=s attorney.

Further affidavits were filed on behalf of the respondents by the deponents to the answering affidavit as well as by the following new deponents: mr Behardien of the State Attorney's office and ms H N Manzini, the acting head of the department of health of the Northern Province.

I shall briefly summarize the main affidavits.

In the founding affidavit of ms Mthathi it is alleged that many public health facilities outside the 18 selected sites are already able to provide the necessary testing and counselling that go with the administration of Nevirapine.

The point is made that the decision to limit the use of Nevirapine to the 18 designated is unfair and restrictive.

The further point is made that the first to nine respondents have no clear plan for a comprehensive roll out of their programme from the pilot sites. They will only be testing implementation for the next two years.

In contradistinction the tenth respondent has a coordinated plan that already reaches 50% of pregnant women in the Western Cape and will have reached 90% in the next phase of the roll out.

The point is made, with reference to a study commissioned by the respondents, that the implementation of a Nevirapine programme will indeed achieve an overall saving, it being cheaper to prevent MTCT than to treat the infected infants for opportunistic diseases that they will contract as a result of their lack of immunity.

Reference is made to several international agreements as further support for the applicant=s case that the Government is obliged to provide anti-retroviral drugs together with counselling and formula feed, where necessary, to all pregnant women. They are the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the African Charter on Human and Peoples= Rights, the Convention on the Elimination of Discrimination Against Women, the Convention on the Rights of the Child and the Convention on Elimination of All Forms of Racial Discrimination.

In his affidavit prof Wood points out that although a few cases of serious side effects of Nevirapine as chronic medication have been reported after ten years of use, there is no evidence of side effects when it is used as a once-off dose.

He stated that the HIVNET012 study in Uganda showed that it achieved better results than AZT. It also had the advantage over AZT that it could be administered in a single dose.

He deals with the issue of resistance to Nevirapine as a result of mutation. He concludes that it causes no harm to the mother and that it is transient.

He discusses breast feeding which accounts for 15 B 44 % of MTCT. At the same time breast feeding remains one of the most effective means of improving a child=s survival, especially in poor countries. He advocates counselling against breast feeding and the providing of formula feed as an alternative.

Dr Karim describes the HIV epidemic in South Africa as explosive. According to him it has not yet reached a plateau.

The figures he gave of its distribution shows that the prevalence in the Western Cape is significantly lower than in the other provinces: 8.7% compared to, say, 29.4% in Gauteng.

He stresses the fact that women are more vulnerable to HIV than men.

According to him tests show that the administration of a single dose of Nevirapine can reduce MTCT by 50%.

Professors Bolton and Cooper, in a joint affidavit, describe how some medical practitioners in the public health sector do manage to made Nevirapine available in spite of the policy of the respondents that the dispensing thereof be confined to the 18 designated sites.

Dr Price expressed the opinion that the prescription of Nevirapine should be left in the hands of practitioners, whether they be in the private or the public sector. He considered it to be in the public interest that it be made available in the public sector.

Prof J Natrass explained what it costs to treat HIV positive children for opportunistic diseases during their short lives. Her analysis shows that the total cost of MTCT prevention programmes, including testing and counselling, is less than the cost of treating HIV positive children. Thus the

implementation of a MTCT prevention programme results in a saving. If AZT is used with breast feeding, the saving is R171-00 per pregnancy. If Nevirapine is used with breast feeding, the saving is R179 per pregnancy. If AZT is used with substitute feeding, the saving is R315 per pregnancy. If Nevirapine is used with substitute feeding, the saving is R341 per pregnancy.

Ms Hardy deposed about the availability of Nevirapine at pharmacies. She points out that out of 20 pharmacies surveyed, 13 did not stock it at all. Of these 13 only 2 had it available in single tablet form. In these cases the prices were R10-56 and R7-72 per tablet.

Ms Mahlonoko is a nurse at the Boipatong Clinic. She described how her work involves HIV testing and counselling. She also does voluntary counselling outside the context of her work.

When she encounters an HIV positive mother who, after counselling, decides to keep her child, she has to refer her to the Chris Hani Baragwanath Hospital for Nevirapine.

In her view Nevirapine should be made available in the public sector. Depending on experience, nurses should be qualified to administer the drug.

She explained the extent of counselling at her clinic. She counsels about 60 people a month in relation to HIV.

Ms Matebula similarly deposed that she does counselling at the Kopanong Hospital in Vereeniging. She has to refer HIV positive mothers, after having counselled them, to the Chris Hani Baragwanath Hospital, some 60 kilometers away.

The affidavits of the women who were tested HIV positive during pregnancy tell the following tales: In one case the mother had been counselled and had received Nevirapine at the Chris Hani Baragwanath Hospital. When she went into labour she did not have the tablet available. Because she delivered at another hospital where Nevirapine was not available, it was not administered to her.

Another affidavit tells the story of an HIV positive child who has been in hospital 14 times with diseases such as pneumonia.

The second applicant, a registered pediatrician, is involved with Save Our Babies (SOB). He works in the Neonatal Unit of the Chris Hani Baragwanath Hospital.

He is of the view that there is no justification to restrict MTCT preventions programmes to pilot and research sites. In his view most major urban hospitals and some peri-urban and rural centers have the resources to implement MTCT programmes.

He contends that the first respondent=s refusal to implement a country wide MTCT prevention programme undermined the clinical independence of health care professionals.

Ms C J Vawda of the Child Rights Centre supported the application. She stated that her centre often has to deal with mothers whose children are very ill or dying, all cases that could have been avoided.

Dr Ntsaluba the Director-General of health deplored the fact that the matter reached the courts.

He contended that the applicants ignore the infrastructural and operational considerations, such as voluntary counselling and testing (VCT), monitoring and evaluation that accompany the administering of Nevirapine.

He also contended that the applicants were in fact advocating what ammounted to a policy choice. According to him the epidemic has reached its plateau in South Africa.

He stated that if Nevirapine was proven to reduce MTCT of HIV even with breast feeding then it could be claimed that it is effective. It is, however, not the case.

He referred to the condition of registration of Nevirapine, which requires the manufacturer to supply a plan for monitoring safety, resistance and lack of efficiency. The research and training sites, which

form an essential part of the national programme, are expected to provide additional data on the efficiency of Nevirapine. At this stage certain safety issues have been identified, like skin reactions such as Steven Johnson syndrome, anaphylaxis and hepatitis. Although these conditions are associated with the long term use of Nevirapine, it is not sure whether they will also occur with short term use.

Then there is the fact that breast feeding is contra-indicated where Nevirapine is used. It is not safe to expose a largely breast feeding population to Nevirapine unless stringent measures are taken.

He alleged that it was the practice all over the world to test drugs that may be used in the public sector. To allow doctors in the public sector to prescribe any drug would case chaos. Budgets would be strained. If all available drugs were to be stored it would lead to wastage.

The respondents could also be exposed to delictual claims if Nevirapine is administered without the necessary support services.

He denied that the respondent's policy is irrational and contrary to the Constitution. The respondents have to balance all the factors in a complex case and have decided to embark on a research and training programme before making Nevirapine available at every public health facility. It is necessary to investigate the side effects if Nevirapine before it is made available at every public health site.

The registration of Nevirapine was based on clinical data from one test in Uganda. The SAINT test in South Africa was inconclusive on efficacy. It failed to prove the superiority of Nevirapine.

One of the reasons for only implementing the MTCT prevention programme at selected sites was to understand the package of care for mothers and babies, especially with regard to breast feeding.

In his view doctors who are flaunting the programme are acting irresponsibly.

It could cause a public health crisis if Nevirapine is administered without the necessary support.

The aim of the respondents is to make Nevirapine available to the general population gradually. It is not practicable to make every public hospital a research site. An incrementalist approach is more consistent with the interests of the public.

He expressed the view that the public sector cannot be compared with the private sector because private practitioners assume personal liability for their decisions.

The respondents must have a complete grasp of the full requirements for a successful MTCT prevention programme so as to make Nevirapine available at all public health facilities.

If state doctors were to be allowed to prescribe any medicine, nothing would prevent them from prescribing expensive drugs for a cardiac condition.

HIV/AIDS is not the only illness that the public hospitals have to contend with. If state doctors were to be allowed to operate outside a fiscal and policy framework, it would throw the public health care system in disarray.

He conceded that MTCT programmes may be cost effective, but pointed out that resources would be needed in the short term.

He denied that the cost of prescribing Nevirapine would be minimal. There are hidden costs and the pilot projects are aimed, *inter alia*, to gather data on these costs.

He denied that there was no clear plan for a comprehensive roll out. In this regard he referred to the affidavit of dr Simelela.

As information is collected and more experience is gathered about the operational challenges, it is envisaged that the programme will be rolled out to other sites. The respondents are keen to

implement an integrated programme as soon as it is reasonably feasible, that is, after their concerns have been addressed.

In the South African context, due to a dearth of resources, the demand for Nevirapine cannot be met immediately.

The cost of a comprehensive programme with AZT would be prohibitive. Nevirapine presented a cheaper alternative. Prior to Nevirapine the available anti-retrovirals were unaffordable.

It is envisaged that the respondents= programme would be extended as lessons are learnt from the various sites.

Dr Simelela is the Chief Director of the HIV/AIDS programme of the Department of Health.

She pointed out that the respondents have embarked on a carefully considered programme for training counsellors and health care workers.

She dealt with the problem of breast feeding. Replacement feeding carried risks associated with malnutrition, especially in the first 6 months. The risk of MTCT of HIV through breast feeding is the greatest during the first 6 months of infant life. There are concerns about mixed feeding and the evidence suggests that the period of transition between exclusive breast feeding and the cessation of breast feeding should be as short as possible.

In the South African context it is essential that there should be training manuals for health workers, that there should be training for VCT, that there should be training on infant feeding and that there should be alternative feeding.

The two sites per province decided on by Minmec are learning sites. It is important that research and monitoring be carried out there so that the whole country can learn from these sites.

The objectives of the research sites are to assess the feasibility of providing VCT services in facilities that provide antenatal services, the acceptability of providing anti-retroviral therapy for the prevention of MTCT, the feasibility of providing counselling on infant feeding procedures, the impact of feeding counselling, the cost of running a MTCT prevention programme etc.

The research programme has three levels, routine monitoring, ordinary research and intensive research.

Several areas of research have been identified. Area A deals with demographic data, area B deals with the infrastructure in the health care system, area C deals with the organization of the health care system, area D deals with statistics, area E deals with a cohort follow up of children, area F deals with the effect of the programme on the rest of the health care system, area G deals with costs and area H deals with the response of the community.

The following has emerged from the sites: all the provinces experience major staffing problems, a shortage of lay counsellors and a lack of stipends for counsellors. There is a shortage of space in health facilities for confidential counselling. Steps had to be taken to extend the shelf life of the Nevirapine syrup that is fed to the infant. It appeared advisable to extend formula feeding to 9 months, because it was reported that infants who had been formula fed for 6 months subsequently presented with malnutrition.

At an international conference she attended in September 2001 it transpired that none of the African countries had a nationwide MTCT prevention programme.

The research and training programme has a cohort follow-up component that is designed to acquire information on the benefits and problems 18 months after delivery.

She stressed the fact that Nevirapine was only found to be effective for the prevention of intrapartum transmission of HIV, not the prevention of MTCT generally.

With regard to mutations she said that mutations cannot be treated with triple drug therapy because it is commonly accepted that that is too expensive for a developing country. Therefor it is essential to understand the effect of mutations. It is not entirely correct to say that mutations are transient.

Although resistant strains of the HIV-1 that had developed in women who were exposed to a single dose of Nevirapine had disappeared from their blood after 6 weeks, other potential implications of resistance should be taken into account. She referred to an article by Mark Wainberg who suggested that long-term studies are needed to determine the duration over which Nevirapine-resistant viruses will persist.

She accepted the World Health Organization=s conclusion that the benefit of reducing MTCT of HIV with anti-retroviral prophylaxis regimes greatly outweighed concerns relating to the development of drug resistance, but pointed out that it recommended further research.

Dr J B Levin is a senior statistician at the MCC.

He confirmed the test that shows that Nevirapine is more efficient than AZT.

With regard to the SAINT study in South Africa, he pointed out that it was a superiority trial and not a non-inferiority trial. It failed to prove the superiority of Nevirpaine.

He concluded that Nevirapine does reduce MTCT but probably by considerably less than the 50% claimed by the applicants.

Dr Makubalo is the Chief Director of Health Information Evaluation and Research in the Department of Health. She is an epidemiologist. According to her the epidemic cannot be described as "**explosive"**. There is a slowing down.

According to her the relative improvement as a result of Nevirapine at week 6 is probably 33%. She denied the allegation that there was overwhelming evidence of the efficacy of Nevirpaine. There is

substantial evidence of reversal at 24 months. It could be as a result of breast feeding. The research programme could cast light on that.

Dr Onyebuyo is a member of the MCC.

He explained that Nevirapine was registered subject to a condition because registration data had been obtained from only one clinical trial conducted in Uganda, and because there was a need for more information regarding safety, efficacy and resistance.

In view of the potential of breast feeding to reverse the initial gains, the MCC insisted that the package insert should make the consumer aware of the impact of breast feeding on the efficacy of Nevirapine.

He pointed out that registration meant that the MCC was reasonably satisfied with the current safety and efficacy data. The magnitude of the impact of HIV is such that it justified an accelerated process with post registration monitoring. This is an internationally accepted phased implementation process.

Then there follow more affidavits on behalf of the second to tenth respondents.

Dr Mjekevu gave figures of the budget of the Eastern Cape. The total health budget for 2001-2002 was R3 835 188 700-00. The health care section has a personnel of 17 335 of which 668 are doctors and 14 111 nurses.

There are 716 clinics. 95,2% of the clinics provide antenatal services.

The AIDS programme has a budget of R33 000 000-00.

Two pilot sites were established pursuant to the Minmec decision at the East London Hospital and at Rietvlei Hospital, a rural hospital which serves 12 clinics.

It is envisaged that as lessons are learnt and resources become available, the programme will be extended progressively.

At present the department cannot implement a comprehensive programme. It is estimated that it will cost R56,9 million, of which R24,3 million will be for counselling and R15,8 million for infant feeding.

The department is unable to implement a comprehensive programme outside the pilot sites immediately.

On behalf of the Department of Health of the Free State Province dr Litlhakanyane stated that pilot sites were established at Virginia and Frankfort, with 20 access points.

To his knowledge no public health facility has the capacity to administer Nevirapine effectively, either immediately or within a short period of time. There is no pool of counsellors and no non-governmental organization are available for counselling..

At present the AIDS budget is R12,383 million. A comprehensive PMTC project would costs R23 million. The cost of the two pilot programmes is R2,115 million.

At present the province cannot extend the programme beyond the pilot sites.

Progressive implementation of a comprehensive programme is an ideal, the pace of which is determined by the availability of resources.

On behalf of the Gauteng Provinc, ms Rispel explained that a HIV research unit was established at the Chris Hani Baragwanath Hospital in 1998. In pursuance of the Minmic decision research units were established at Natalspruit Hospital and the Kalafong /Pretoria West Hospital. The site in Natalspruit commenced on 21 May 2001, and the one at the Kalafong/Pretoria West on 8 June 2001. Additional sites have been identified: Leratong Hospital as from 12 September 2001, Coronation

Hospital as from 12 September 2001, Johannesburg Hospital as from 1 October 2001, Sebokeng Hospital as from 30 November 2001 and Garankuwa Hospital as from 28 February 2002.

To make Nevirapine immediately available at all public health facilities is not possible due to a lack of human resources.

Counsellors are drawn from non governmental organizations. Counsellors attend to 8 to 10 patients per day, with sessions taking 40 to 60 minutes per patient.

The total AIDS budget is R73,5 million.

Dr Green-Thompson, the head of the Health department of KwaZulu Natal, stated that the province is not in a position to implement the programme for prevention of MTCT of HIV comprehensively. That is so for a shortfall in financial allocation and because of logistical issues. From the pilot sites problems relating to physical and human resources have been reported.

The cost of a comprehensive programme has been calculated to be R30 million, but it is more likely to be R48 million.

The department is not in a position, from a resource point of view, to implement a comprehensive programme immediately or in a short space of time.

There are presently 10 access points around the two pilot sites.

There are 396 clinics and 61 provincial hospitals. The department employs 2 232 doctors and 23 236 nurses. Many posts are vacant as a result of a shortage of skills and funds.

There are four non-governmental organizations involved in counselling.

Lay counsellors are used but their number is insufficient.

In his view a progressive roll out of the programme to other sites, as and when resources become available, is the most rational approach.

Ms Charles, the head of the Mpumalanga Health Department, stated that the current health budget was R1,411 billion. The department had 5 313 nurses and 443 doctors. There are 386 clinics and 25 hospitals. 98,2% of clinics provide antenatal services.

The HIV/AIDS programme has a budget of R7,122 million. R2 Million is devoted to the MTCT prevention programme.

For the pilot programme existing staff was recruited and trained.

Owing to a lack of resources it is impossible to implement a comprehensive programme outside the pilot sites immediately.

Dr Hendricks, the head of the Department of Health of the Northern Cape, confirmed that two pilot sites had been established at the Galeshewe Day Hospital in Kimberley and the De Aar Hospital. Those sites serve 12% of the population of the province.

The cost of the programme at the two sites is R1,651 million. If it is extended to the whole province, an additional R14,2 million will be required.

He sketched the problems posed by the fact that the province comprises 30% of the land mass of the country, but only houses 2% of its population. So, of the 88 clinics, 34% have only one professional nurse.

The expansion of the MTCT programme will necessitate the appointment of additional professional staff.

No health facility in the province can immediately take on a comprehensive MTCT programme. Two facilities that would require the least preparation for an expansion of the programme are the Upington and Kimberly Hospitals. Even that would require extensive preparation.

In his view a progressive implementation of a comprehensive programme, as resources allow, is the most feasible.

Dr Thobejane, the head of the Department of Health of the Northern Province, stated that there are 474 clinics in the province that provide antenatal and post natal services. Of these 169 provide 24 hours maternity services. There are 43 hospitals.

There was a critical shortage of personnel in the department. He can testify that the pilot site at Mankweng is not coping with the added responsibilities of the MTCT programme. Lay counsellors had to be appointed.

The health budget is R1,5 billion and the HIV/AIDS budget is R7 million. The amount allocated for the two pilot sites is R1.7 million.

The pilot sites comprise 20 clinics.

A comprehensive programme will cost R71 million.

If a comprehensive programme is embarked upon, other health services will suffer. The more reasonable approach is to learn from the pilot sites and extend the programme as resources become available.

To his knowledge there is no public health facility outside the pilot sites and access points that has the capacity to administer Nevirapine properly.

Dr Gosnell, the head of the Health Department of the North West Province, stated that the fight against HIV/AIDS remains one of his department=s priorities and that the provision of Nevirapine was part of its programme to deal with HIV/AIDS.

In order to provide Nevirapine an infrastructure had to be developed to provide counselling and alternatives to breast feeding.

A point has been reached where out of the 344 facilities 144 already provide VCT.

He sketched the problems with the training of counsellors and the attrition rate of counsellors. Health institutions did not have counselling facilities.

In respect of breast feeding the department is in the invidious position that, having previously encouraged breast feeding, it must now reverse the culture.

The pilot sites established pursuant to the Minmec decision are to be run for 18 months. Then the programme is to be rolled out to the whole of the province provided that the pilot sites are successful.

In his view it would be difficult and irresponsible to provide Nevirapine to the whole province immediately. The data collected at the pilot sites will enable the department to undertake the planning to ensure an effective implementation of a comprehensive programme.

Dr Abdullah, the Deputy Director-General of the Department of the Western Cape Province, stated that his province was already implementing and rolling out, on a phased basis, a plan to reduce MTCT of HIV.

At present the programme has reached 50% of HIV positive women. By 30 June 2002 it will have reached 90%. By March 2003 coverage will be 100%.

The province commenced its first MTCT site in Kyalitsha in January 1999 using AZT. AZT had to administered twice daily from the 34th week of pregnancy till the onset of labour, and then every three hours until the baby was born. Mothers were counselled to use formula feed and they were provided therewith.

After the success of the Khyalitsha pilot site the project was expanded to five other sites. In the first phase of roll out further sites were added. The second phase of roll out covers the period 1 September 2001 to 31 January 2002. Phase 3 will cover the period April 2002 to June 2002 and phase 4 July 2002 to March 2003.

Detailed plans for phases 3 and 4 have not been finalized because it is considered unrealistic to embark on detailed planning more than 12 months in advance.

In remote and sparsely populated areas mobile clinics will be used.

It is not possible to achieve a universal roll out in the province overnight.

Counselling is provided by means of full time dedicated and trained counsellors. Training consists of a two day course for clerks, a four day course for nurses, and a 15 day course for counsellors.

Each site keeps records, which allows for monitoring.

The budget allocation for the current year is R7,6 million. In addition the University of Cape Town has contributed R4,4 million. In the 2002-2003 year it will increase to R15 million and the contribution of the University of Cape Town is expected to be R6 million.

In facilities outside the programme, to avoid so-called missed opportunities, a policy has been devised to allow a clinician to prescribe Nevirapine after consulting the medical superintendent of the facility in question. The medical superintendent is empowered to authorize the prescription of Nevirapine after having regard to the financial situation of the particular facility. The HIV status of

the patient must have been established by testing. Counselling should also be applied. For those women who choose to use formula feed an adequate supply of formula feed should be available for at least 6 months post partum.

The policy avoids a situation where Nevirapine is automatically prescribed to all women suspected of being HIV positive.

He does not agree that the prescription of Nevirapine should solely be governed by the relevant state doctor. That would be inappropriate in the public sector.

The tenth respondent continues to prescribe AZT at its pilot project in Khayalithsa. It wishes to continue to do so for comparative purposes. Prayers 1 and 2, if granted, appear to preclude the tenth respondent from doing that.

In the replying affidavit of Ms Mthathi the point is made that it is not the applicant=s case that Nevirapine should be provided immediately to every pregnant woman who is HIV positive. Their case is that the respondents have failed to design a programme to provide treatment on a comprehensive and nationwide basis.

The point is made that where infants became HIV positive as a result of breast feeding, it is the breast feeding, and not Nevirapine, that is the cause of the transmission of the virus.

The inference is made from the affidavit of dr Ntsaluba that the respondents have not taken any decision to institute a nationwide programme because it is not considered possible to determine the cost Beffectiveness of Nevirapine until babies have been treated at the pilot sites for 18 to 24 months.

In respect of prayers 1 and 2 she made it clear that the applicants accepted that there should be informed consent.

Dr Folb, a former member of the MCC ,explained that the registration of Nevirapine implied that the MCC was of the view that the drug was safe and efficacious. The condition imposed was not extraordinary. The drug could be used.

Dr Wood, in his replying affidavit, accepted that there is no easy answer to operational challenges. He suggested a two-fold approach: firstly doctors and other health professionals in the public health sector should be allowed to prescribe and administer Nevirapine anywhere where the capacity exists to counsel and where patients have given informed consent. Secondly a comprehensive plan must be adopted to provide for the training of health care professionals, counsellors, testing, the providing of food supplements etc.

Dr Pierre Schoeman, a pathologist stated that he had done HIV resistance testing over 18 months. In his view Nevirapine is unlikely to cause widespread HIV resistance.

Nevirapine does not cause the mutation that can lead to drug resistance. It merely provides a favourable environment for already resistant viruses to become the predominant virus. After discontinuation of Nevirpaine the drug free environment will allow the wild type virus to reestablish itself as the predominant virus.

Mutations that cause Nevirapine resistance also do not affect the efficacy of the two other classes of drugs that remain available.

Dr Mark Wainberg of the McGill University commented on an article written by him and cited by dr Ntsaluba.

In his view the use of Nevirapine should be encouraged. The effectiveness of the drug should take precedence over considerations of drug resistance.

Dr Cooper confirmed that his evidence about what practitioners in the public sector are doing is based on personal experience. At the Johannesburg Hospital Nevirapine was obtained through a

donation from a church. It was administered after testing and counselling. Since 1 October 2001 they were allowed to administer Nevirapine without additional staff.

Professor Natrass, in a replying affidavit, demonstrated that there would still be a saving if substitute feeding were to be given up to 12 months.

Professor Schneider addressed the issue of the capacity of the public health sector to implement a MTCT prevention programme beyond the pilot sites, whether now or later.

She pointed out that 94% of women use antenatal services. 84,4% of them deliver in the system. 93,3% of children attend health facilities for their first immunizations. 56,2% of fixed clinics offer HIV testing. 83% of fixed clinics provide HIV couselling. The daily patient load of nurses was well within accepted norms.

Her conclusion is that the health system has the immediate capacity to provide a MTCT prevention programme on a larger scale than at the pilot sites in at least 8 provinces. She excluded the Northern Province, where 14,6% of clinics had HIV testing facilities. In her view the marginal cost of a passive extension of the programme would be small.

In respect of an extension towards universal access she concluded that an uneven implementation would occur owing to inequality between provinces.

Mr C Allan, the director of the Public Service Accountability Monitor at Rhodes University, pointed out than in the Eastern Cape for the 2000-2001 year R33 million had been allocated to HIV/AIDS projects. According to the report of the Auditor-General that amount was transferred to the Fort Hare Foundation.

Dr L Guay of the John Hopkins University, testified that she was involved in the HIVNET 012 study in Uganda.

In her view Nevirapine has been shown to be safe and effective. It has became the drug of choice in countries where a simple and inexpensive method of prevention is required.

The HIVNET012 study was conducted in a breast feeding population.

Nevirapine does not allow the virus to become resistant to it. Its presence in the body allows an existing virus to become the predominant virus whilst other predominant viral variants are suppressed. When Nevirapine is no longer present, the non-resistant virus again becomes the predominant virus. Viral resistance is a problem with all anti-retroviral drugs.

In respect of breast feeding she stated, with regard to the Ugandan test, that there were new infections as a result of breast feeding. The women who participated in the test were not provided with free formula feeding. The benefits of Nevirapine were registered despite a high frequency of breast feeding. Thus the avoiding of breast feeding is not a prerequisite for the success of Nevirapine.

Dr H Reuter gave particulars of the Khaylitsha project.

Dr A H Grant, the Acting Medical Superintendent of the Bethesda Hospital at Ubombo in KwaZulu Natal, expressed the opinion that his hospital is in a position to implement a programme for the administering of Nevirapine.

Doctors in the hospital have in fact bought Nevirapine with their own money and dispensed it to patients who had given their informed consent. Their protocol was based on that of the McCord Hospital in Durban.

Further affidavits were filed by the respondents to deal with what was considered to be new material in the replying affidavits.

I shall only refer to some.

Dr Ntsaluba responded to dr Folb=s affidavit by stressing the need to continually seek data to support the initial data on which approval was based.

In respect of dr Schneider=s affidavit he said that the programme to expand access to VCT was started two years before the establishment of the research and training sites. The training did not go into any significant detail in the context of the prevention of MTCT. Although counselling is offered at 83% of fixed clinics, the health workers are not fully capable of providing VCT in the context of the prevention of MTCT.

With regard to dr Grant=s affidavit he said that it took 6 months to train counsellors after they have been identified. Then they need a further 3 months in-service training and a further 6 months of working under supervision.

He considered it ethically wrong to dispense Nevirapine to women irrespective of whether they have been tested positively for HIV, as he apparently presumed was suggested by dr Grant.

On behalf of the Eastern Cape Province, dr Mjekevu explained the transfer of R33 million to the Fort Hare Foundation. Because certain vital posts could not be filled, the department sought the assistance of the Fort Hare University. Later it became clear that the correct tender procedures had not been followed. As a result the department had to return the R33 million to the Treasury. The failure to use the money was not deliberate.

Mr Marcus SC who, with mr Majola, appeared for the applicants argued that there is no dispute that Nevirapine is effective in reducing MTCT of HIV.

He argued that the argument about the safety of Nevirapine was misplaced in view of the fact that it was registered for the reduction of MTCT. He contended that the real issue concerned those who, by reasons of geographical location, are excluded from receiving Nevirapine at the 18 selected sites.

The conditional registration of Nevirapine he described as a misnomer. He pointed out that it was available for use, as medically indicated, without restriction. The condition imposed on registration was imposed on the manufacturer.

In respect of breast feeding he pointed out that though breast feeding was a method of MTCT, it does not follow that if there is breast feeding, the virus would be transmitted. According to one study, breast feeding reduces MTCT by 44%.

He argued that the concerns expressed about the need to investigate drug resistant mutations of HIV overstate the risk. The evidence was that the mutations were transient.

In respect of the cost of Nevirapine, he argued that the cost of the drug was less than R10-00 per treatment. The major costs were those relating to counselling and formula feeds.

He contended that there was an absence of rationality in the selection of the designated sites, amongst others in the exclusion of areas where expertise and resources were available.

He referred to the situation in the various provinces and submitted that the Western Cape stood alone in having a comprehensive plan to ensure that all HIV positive women would have access to Nevirapine and the necessary support services.

Whilst accepting that the provinces had budgeting constraints, he pointed out that in the 2000 - 2001 year two of them did not spend their total allocation for health and that only 66% of the R15 million provided by the national government for HIV aids was spent.

He questioned the alleged lack of capacity to administer Nevirapine where the evidence was that 94% of South African women make use of antenatal services during pregnancy and 84,4% delivered under supervision of a health professional.

He took issue with the statement of dr Ntsaluba that allowing doctors in the public sector to prescribe Nevirapine would cause chaos. In this respect he referred to the practice in the Western Cape, where public health doctors are allowed to prescribe the drug in consultation with the medical superintendent.

He pointed out that the evidence on behalf of the applicants that there are practitioners in public hospitals who do administer Nevirapine was not denied. It was only alleged that they were flaunting authority.

He contended that the availability of Nevirapine in the private sector has the effect that the respondents= policy discriminates against people on the ground of poverty.

He submitted that if private practitioners are competent to prescribe Nevirapine where it is medically indicated there is no reason to assume that practitioners in the public sector are not equally competent. The effect of the respondents= policy, he argued, was to cause an ethical dilemma for doctors in State hospitals.

He argued that the applicants= evidence of the cost benefits of Nevirapine was uncontested.

On the law, he referred to Government Notice 657 of 1 July 1994, and argued that by denying pregnant women outside the designated sites access to Nevirapine, the respondents were acting *ultra vires* their own policy.

He argued that Government Notice 657 was applied in a way that was unequal and unjust. He also argued that it gave rise to a legitimate expectation, which expectation had been thwarted by the conduct of the respondents.

Then he referred to several sections of the Constitution of the Republic of South Africa, Act 1996, (Act 108 of 1996 (the Constitution): section 7(3) which places a duty on the State to respect, protect, promote and fulfil the rights in the Bill of Rights, section 237 which requires that all constitutional

obligations must be performed diligently and without delay, section 27 which provides for access to health care services, including reproductive health care, section 28(1)(c) which provides for basic health care for children, section 9 which guarantees the right to equality, section 10 which enshrines the right to human dignity, section 11 which protects the right to life, section12(2)(a) which accords the right to bodily and psychological integrity, which includes the right to make decisions concerning reproduction, and section 195 which requires, *inter alia*, that public administration must be governed by the democratic values enshrined in the Constitution and that a high standard of professional ethics must be promoted and maintained.

He argued that the implementation of the MTCT prevention programme and the prohibition on the use of Nevirapine outside designated sites resulted in a violation of the human rights entrenched in sections 28(1)(c), 10, 9, 11 and 12(2)(a) of the Constitution.

He emphasized that the respondents could not rely on any law of general application to limit those rights. In this regard he referred to **Premier Mpumalanga v Association of State-Aided Schools 1999(2) SA 91 CC at 110 F - G.**

The decision to prohibit practitioners in the public sector to prescribe Nevirapine he considered as a violation of section 195.

With regard to the interpretation of the Constitution, he referred to section 39(1)(b) which enjoined a court to consider international law. He referred to several international instruments like article 25 of the Universal Declaration of Human Rights, 1948, The International Covenant on Economic, Social and Cultural Rights, Article 24 of the Convention on the Rights of the Child, 1989, and the Convention on the Elimination of All Discrimination Against Women, 1979.

In regard to the ambit of constitutional control of administration action, he referred the court to **The Pharmaceutical Manufacturers Association of South Africa and another: In re: ex Parte President of the Republic of South Africa and others 2000(2) SA 674 CC at paragraphs 85, 86 and 90.**

Apart from relying on Government Notice 657, he relied on a breach by the respondents of the State's positive obligation to promote access to health care in terms of section 27(2) of the Constitution.

He referred the court to **Government of the Republic of South Africa and others v Grootboom and others 2001(1) SA 46 CC** at paragraph 34. He argued that the refusal to permit doctors in the public health sector to dispense Nevirapine was a breach of the negative duty referred to in paragraph 34 of the judgment in the **Grootboom case** *supra*.

With regard to the duty to take reasonable measures to promote access to health care, he referred extensively to the **Grootboom case** *supra*.

In that context he argued that the programme of the respondents was not coherent, was not reasonable, lacked balance and flexibility and was not a systematic response to a pressing social need.

Apart from section 27(2), he contended that the conduct of the respondents involved a breach of sections 28, 11, 10, 12(2) and 9 of the Constitution.

With regard to section 195 of the Constitution, he argued that it was justiciable . In this regard he referred the court to **President of the Republic of South Africa and others v South African Rugby Football Union and others 2000(1) SA CC at paragraph 134.** He contended that the requirement of a high standard of professional ethics is compromised by the respondents= refusal to allow doctors in the public sector to dispense Nevirapine.

As far as the relief claimed is concerned, he pointed out that prayers 5 to 8 are in conformity with relief granted by the Constitutional Court in **August & another v Electoral Commission and others 1999(3) SA 1 CC at paragraph 42.**

Mr Moerane SC, who with mr Coppin and mr Vally, appeared for the respondents, made the point *in limine*, that the applicants should have cited the Government of the Republic of South Africa and not the various respondents. He argued that each respondent could only be held responsible within the parameters of his budgetary allocation.

He argued that the applicants are in fact urging the court to make a policy choice and to enforce what, according to the applicants, would be a better choice.

He submitted that the decision of the respondents to embark on a research and training programme was reasonable, rational, *bona fide*, justified and consistent with the State=s obligations in terms of section 27 of the Constitution.

He argued that the applicants' deponents ignored the infrastructural and operational considerations that accompany treatment with Nevirapine, such as testing, counselling, monitoring and the need to be alert to the development of resistant strains.

He pointed out that the respondent=s approach was consistent with the condition imposed when Nevirapine was registered.

He referred to the answering affidavits to show that the benefits of Nevirapine have not been established as clearly as portrayed by the applicants.

He argued that the respondents have already embarked on a carefully planned programme in all provinces and that a dearth of resources makes it impossible to implement it immediately.

He submitted that the main issue was whether the respondents have complied with the State=s obligations in terms of section 27(1) and 27(2) of the Constitution. He accepted that section 27(2) imposed a positive duty on the state to take reasonable legislative and other measures within its available resources to achieve the progressive realisation of everyone=s right to access to healthcare services. In the context of the reasonableness of the steps taken by the respondents, he emphasized

the constraints imposed by limited resources and referred to **Soobramoney v Minister of Health, Kwa-Zulu Natal 1998(1) SA 765 CC para 31.**

He argued that the case of **Government of the Republic of South Africa v Grootboom & others 2001(1) SA 46 CC** was distinguishable in that it concerned the duty to provide housing.

He argued that if the relief claimed by the applicants were granted, it would amount to a breach of the separation of powers. In this regard he referred to **Du Plessis and others v De Klerk and another 1996(3) SA 850 CC at paragraphs 180 and 181.** He also referred to the judgment of **S v Lawrence, S v Negal, S v Solbern 1997(4) SA 1176 CC at paragraphs 42 to 44.**

He submitted that MTCT for HIV is but one facet of health care, and to prioritize it would lead to budgetary distortions.

With reference to **Grootboom=s case** *supra*, he argued that a child=s rights in terms of section 28(1)(c) of the Constitution are not independent of the rights conferred in section 27, and are in fact subject to the provisions of section 27(2).

In respect of Government Notice 657 of 1994 he argued that it only referred to "**all available health services"** and not to **"potentially available health services"**.

Inasmuch as the applicants relied on legitimate expectation, he submitted that it could not create substantive rights and referred to the unreported judgment in **Leonardo Safari's v The Premier of Gauteng Province,** case no 98/18201 WLD, delivered on 20 July 1999.

He stressed the fact that Nevirapine had long term undesirable side effects and that it was conditionally registered on the result of only one test, the HIV NET 012 that was conducted in Uganda.

He argued that the respondents decision to embark on a research and training programme at selected sites was responsible and correct.

The respondents' programme was designed to ensure a collection and evaluation of data so that the lessons learnt from all provinces could be coordinated. He referred to lessons already learnt, namely the need for training on VCT and MTCT, the need for space for VCT, that the period over which free formula milk is to be provided should be extended, etc.

He referred *seriatim* to the details provided by the various respondents relating to their budgets and human resources and argued that it underscored the correctness of the approach of a progressive roll out of the programme initiated at the training sites.

In respect of prayers 1 and 2 he argued that good governance required that health professionals in the public sector work within a policy and fiscal framework in order to ensure the maximum and fair utilization of resources.

He warned of moral and ethical issues that may arise if public health professionals with divergent views, like the deponent dr Grant, were to prescribe Nevirapine to all pregnant women, irrespective of their HIV status.

He argued that the relief claimed in prayers 3 to 8 is based in the misconception that the respondents had not taken appropriate measures within their resources. In this regard he referred, amongst others, to the HIV/AIDS Sexually Transmitted Disease Strategic Plan for South Africa 2001 - 2005. He submitted that if relief could not be granted in respect of prayers 1 and 2 it followed automatically that relief could not be granted in terms of prayers 3 to 8.

On a conspectus of the papers, he argued, that the applicants= case boiled down to a demand for a detailed time table for a roll-out of treatment with Nevirapine throughout the country. He referred to the example of the Western Cape, whose department had stated that it was unrealistic to embark on detailed planning and scheduling more than 12 months in advance.

He asked that the application be dismissed.

In my view there is no merit in the submission on behalf of the respondents that the Government of the Republic of South Africa should have been cited as a respondent. Section 2 of the State Liability Act 1957 (Act 20 of 1957) expressly permits, but does not prescribe, the citation. It is also possible for a litigant to sue the Government of the Republic of South Africa *eo nomine*. See **Regering van die Republiek van Suid-Afrika v Santam 1964(1) SA 546 W at 548 D - E.**

Section 2 of the State Liability Act will make no sense if the minister who may be cited is not cited as the representative of the State in the litigation. The minister is a member of the cabinet and as such a member of the national executive. It can only make sense that he will represent the Government in litigation where he is cited as the nominal defendant.
I can see no reason why a minister cannot represent the state where the outcome of litigation will have a financial impact that exceeds his budget.

Section 2 does not say that a minister may only be cited in certain circumstances. It creates an unlimited right to sue the minister concerned, instead of the Government. In my view nothing more need to be read into section 2 than that it intended to allow of a more focused procedure, more focused on the member of the executive who is directly concerned with the litigation.

The point *in limine* that the Government should have been cited, is therefore dismissed.

Where this is an opposed application where final relief is sought, the principles enunciated in **Plascon-Evans Paints v Van Riebeeck Paints 1984(3) SA 620 AD at 634 E - 635C** are applicable.

In spite of many denials and counter denials there are not so many factual disputes in this matter. Very often the differences are differences of emphasis and approach. I shall, however, remain mindful of the approach laid down in the **Plascon-Evans** case *supra.*

I am in agreement with mr Moerane that the matter should be approached from the perspective of section 27(2) of the Constitution. The question is whether the first to ninth respondents have taken reasonable legislative and other measures within their available resources to achieve the progressive realisation of the right to health care services, including reproductive health care.

In determining whether such measures as have been taken are reasonable, it will be a relevant factor that other fundamental rights are involved. See the **Grootboom** case *supra* at p83, para 83.

It is therefore of importance that not only the right to health care is at stake, but also the rights afforded by sections 9, 10, 11, 12(2)(a) and 28(1)(c).

In my view Government Notice 657 of 1 July 1994, published in Government Gazette 15817, does not take the matter much further. It does not deal with the availability of health services and with what health services should be available. It does not confer any entitlement as such to health services. It merely provides that certain categories of patients are absolved from payment for health services. What it does, is not be expand health services, but to make health services free for certain people.

That that is the position appears from the title of the proclamation and the recurrent use of the phrase "**free health services"** in it. It also appears from section 3 which reads: **(3) Free health services include the rendering of all available health services to the persons mentioned in paragraph (1), including the rendering of free health services to pregnant women for conditions that are not related to pregnancy .**

To the extent that the proclamation has ensured that pregnant mothers who are HIV positive, and who have access to a facility where a programme for the prevention of MTCT of HIV is available, do not have to pay for such treatment, it has contributed to a progressive realisation of the right to health services as provided in section 27(2).

The applicant invoked the doctrine of legitimate expectation in conjunction with Government Notice 657. I am in agreement with what was said in the case of **Leonardo Safari=s** *supra*, cited by mr Moerane, that a legitimate expectation cannot be relied to confer substantive rights. It can be used as the basis of a claim to fair procedural treatment. This case concerns medical treatment by virtue of alleged substantive rights.

The real issue is whether the steps taken by the first to ninth respondents with regard to the prevention of MTCT of HIV by establishing 18 pilot sties and confining the dispensing of Nevirapine to those sites, can be considered to be a compliance with the obligation of the State in terms of section 27(2).

It is clear, in my view, if one has regard to the **Grootboom** case *supra*, that the obligation of the State in terms of section 27(2) is justiciable. See, for instance para 94 at p 86. That case concerned section 26(2), which, in the context of housing, is similarly worded to section 27(2). In that case the court measured the steps taken by the state in the progressive realisation of the right to housing and in the end found them to be wanting.

The arguments by mr Moerane that to grant to the relief asked would entail a breach of the separation of powers and the making of a policy decision miss the point. Where the court, being a part of the judicial arm of government, sits in judgment on the reasonableness of steps taken by the executive arm in the fulfillment of its constitutional obligations, it is exactly a perfect example of how the separation of powers should work.

The court does not assume the task of the executive when it pronounces on the reasonableness of steps taken by the executive in the fullfilment of a constitutional obligation of the State.

In Mohamed and another v **President of the Republic of South Africa and others 2001(3) SA 893 CC at paras 69 to 71,** it was said that it would negate the supremacy of the Constitution if a court could not pronounce on the validity of executive action. The same would apply if the court could not pronounce on the reasonableness of steps taken by the state in the fulfillment of its constitutional

obligations. The argument that to make an order as prayed would be tantamount to a policy decision does not take account of the fact that the court is required to pass a value judgment as to whether steps taken in order to effect a gradual realisation of a constitutional right were reasonable.

I shall accept that the respondents had to make policy decisions, and that there need not be one objectively determinable road to the progressive realisation of the right to health care, but in the end the court has to determine whether the steps taken by the respondents were, in the circumstances, reasonable. That is the constitutional imperative.

I find the case of **Grootboom** ***supra*** most instructive. Mr Moerane has argued that it is distinguishable because it deals with housing. He urged me to follow the approach set out in the case of **Soobramoney** ***supra.*** The fact is that it is exactly the case of Soobramoney that is distinguishable. It deals with a different right, the right not to be refused emergency medical treatment in terms of section 27(3). Although a right related to health care, it is not a right in respect of which the state has the obligation to achieve its realisation progressively. In that respect the case of **Grootboom** ***supra*** is in *pari materia* with this case.

Although prayers 1 and 2 are different in form from prayers 3 to 8, they all flow in my view from a case based on an alleged failure by the state to comply with its obligation in terms of section 27(2). The relief asked in prayers 1 and 2 relates to a crisp issue which is capable of relief by interdict. They relief claimed in prayers 3 to 8, clearly based on the case of **August** *supra*, is the only relief a court could grant for a more generalized failure to take reasonable steps towards a progressive realisation of the right to health care. If the court were to go further it would indeed be making policy decisions and usurping the functions of the executive.

To return to the **Grootboom** case: the following passage should be borne in mind: at p 67 H – I: **"However ss (2) also makes it clear that the obligation imposed upon the State is not an absolute or unqualified one. The extent of the State's obligation is defined by three key elements that are considered separately: (a) the obligation to 'take reasonable legislative and**

other measures'; (b)'to achieve the progressive realisation' of the right; and (c) 'within available resources".

At p 68 B – C: **"A reasonable program therefore must clearly allocate responsibilities and tasks to the different spheres of government and ensure that the appropriate financial and human resources are available".**

At p 69 B – C: **"The State is required to take reasonable legislative *and* other measures. Legislative 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 programs implemented by the Executive. These policies and programs must be reasonable both in their conception and their implementation. The formulation of a program is only the first stage in meeting the State's obligations. The program must also be reasonably implemented. An otherwise reasonable program that is not implemented reasonably will not constitute compliance with the State's obligations".**

At p 69 E: **"The program must be balanced and flexible and make appropriate provision for attention to housing crises and to short, medium and long term needs. A program that excludes a significant segment of society cannot be said to be reasonable. Conditions do not remain static and therefore the program will require continuous review".**

At p 69 I to p 70 B: **"The extent and content of the obligation consist in what must be achieved, that is, 'the progressive realisation of this right'. It links ss (1) and (2) by making it quite clear that the right referred to is the right of access to adequate housing. The term 'progressive realisation' shows that it was contemplated that the right could not be realised immediately. But the goal of the constitution is that the basic needs of all in our society be effectively met and the requirement of progressive realisation means that the State must take steps to achieve this goal. It means that accessibility should be progressively facilitated: legal, administrative, operational and financial hurdles should be examined and, where possible, lowered over time.**

Housing must be made more accessible not only to a larger number of people but to a wider range of people as time progresses.

At p 71 A: **"There is a balance between goal and means. The measures must be calculated to attain the goal expeditiously and effectively but the availability of resources is an important factor in determining what is reasonable."**

At p 78 I: **"But the question is whether a housing program that leaves out of account the immediate amelioration of the circumstances of those in crisis can meet the test of reasonableness established by the section."**

At p 79H: **"Effective implementation requires at least adequate budgetary support by national government. This, in turn, requires recognition of the obligation to meet immediate needs in the nationwide housing program."**

At p 86 F – G: **"However, s 26 does oblige the State to devise and implement a coherent, co-ordinated program designed to meet its s 26 obligations."**

Against this background I shall now deal with the issue of whether the respondents have fulfilled their constitutional obligations in terms of section 27(2).

Section 27(2) clearly presupposes a situation where there is not yet a full realisation of the right to health care. No doubt that is in recognition of a host of historical and socio economic realities. It equally imposes the duty to achieve a progressive realisation of the right to health care as an ongoing obligation. It obviously does not impose the duty to achieve the realisation of access to health care overnight. The pace is dictated by available resources. Yet, in my view the inexorable goal is a realisation of the right, even through it may be achieved progressively.

What is in issue in this case is not the general implementation of health care. This case concerns merely an aspect of it, namely a programme for the prevention of MTCT of HIV. Although it is only

a facet of health care. This case concerns merely an aspect of it, namely a programme for the prevention of MTCT of HIV. Although it is only a facet of health care, in view of what is at stake, it is a very important aspect of health care.

Mr Marcus conceded, correctly I think, that there is nothing wrong per se with a gradual geographical roll out of a comprehensive programme of health care relating to MTCT. It is in keeping with the duty to provide achieve a progressive realization of the right to health care within the state's available resources.

In that context I am also of the view that the respondents cannot be faulted for having decided to establish two research and training sites, or pilot sites, in each province. With a recently registered drug it cannot be denied that it is a prudent precaution to have centers where track is kept of its performance so that counter-indications can be picked up.

Furthermore the research and training sites also provide valuable information about the logistical and operational problems that can be encountered in the implementation of a programme for the prevention of MTCT of HIV.

Having said that, it must not be forgotten that the phased implementation of a health care programme is discriminating, that it causes inequality and that it denies access to those who find themselves outside the reach of the sites where implementation is being effected.

Much as made of the conditional registration of Nevirappine and its possible side effects. The evidence was that the side effects are associated with long-term use, not with the once-off use for the prevention of intrapartum MTCT of HIV. The evidence was also that the mutations that lead to resistance are transient and disappear when Nevirapine is not longer in the body.

The evidence is also that the conditional registration, or accelerated registration, is a mechanism to make a drug immediately available where the available evidence is that it is safe and efficacious. It is a procedure that is resorted to where the health authorities are faced with a crisis of the first

magnitude, such as HIV/AIDS. The approach is to provide the public with immediate access to the drug for the good it can do whilst at the same time imposing conditions to ensure the collection of long term data relating to its effect. In view of all this evidence there is in my view no justification to suggest, if there is such a suggestion, that Nevirapine should not be made generally available to the South African public because of its conditional registration or because of reservations about sie effects or resistance. It can be made available for general use. The fact that its use may have to be monitored does not detract from the fact that it is available for general and large scale use.

Another subject that enjoyed much attention was breast feeding. Dr Ntsaluba stated that it would be irresponsible for the first to ninth respondents to make Nevirapine available in the entire public sector where it is common knowledge that a percentage of babies who are born HIV negative subsequently become HIV positive as a result of breast feeding. The point is that if a baby is born HIV negative because Nevirapine was administered during delivery and subsequently becomes HIV positive as a result of breast feeding, it is the breast feeding, and not the Nevirapine that has caused him to become HIV positive. It would be irresponsible to administer Nevirapine to the mother without counseling her as to the risks of breast feeding. As it is, the evidence shows that breast feeding does not necessarily reverse the effect of an intrapartum application of Nevirapine. It is of note that according to dr Guay the Ugandan study was conducted in a breast feeding population without substitute feed being made available. According to a study cited by Dr Wood and apparently accepted by dr Ntsaluba, the avoidance of breast feeding can reduce MTCT by 44%. Obviously, to optimize the effect of Nevirapine, or rather to avoid reversals, it is the better option to provide formula food for those mothers who are prepared not to breast feed, but who cannot afford formula feed. That is also why it is quite correct that where the respondents have implemented a programme for the prevention of MTCT of HIV, they have done so with formula feed as part of the package. All that does not mean, however, that before full implementation, it would be irresponsible after proper counseling, to prescribe Nevirapine without the availability of formula feed.

I shall now deal with the relief claimed in prayers 1 and 2.

There is in my view incontrovertible evidence that there is a residual or latent capacity in the public

sector outside the 18 pilot sites to prescribe Nevirapine. The experience in the Western Cape is evidence of it. Dr Cook testified to it in relation to the Johannesburg Hosppital. Dr Grant testified to it in respect of a rural hospital in KwaZulu Natal. The suggestion that he is in favour of prescribing Nevirapine to women regardless of their HIV status is wrong. He merely cited an Africa Centre report which suggested it as a cheaper alternative. Further support of the residual capacity in the public sector to prescribe Nevirapine is to be found in the affidavits of nurses Matebula and Mahlonoko. The evidence of the number of hospitals in the provinces also points to such a capacity. Then there is the evidence of prof Schneider which cannot be denied. The very fact that in Gauteng it was possible to effect such a rapid extension of the programme shows that there is an existing capacity that can be harnessed.

The arguments against allowing doctors in the public sector to prescribe Nevirapine are mainly that it would throw the system in disarray, that it would cause budgeting distortions, and that it would set a precedent for the prescription of expensive drugs for the most esoteric conditions. I cannot agree with these arguments. We are not concerned with the prescription of an expensive drug. Its cost is minimal, if it is to have a price at all. If the respondents are ordered to make it available, it enters, as it were, the Essential Drug List, and its prescription can set no precendent. There is no evidence that the prescription of Nevirapine in this way has caused any chaos or disarray in the Western Cape. What it has done, as pointed out by dr Abdullah, was to avoid so called missed opportunities. In other words it mitigated the harsh and discriminating effect of the decision to start the programme at two pilot sites in the province. To that extent it was also a means of the progressive realization of the right to health care, in this case by means of access to Nevirapine, in the province. I agree that state doctors should not be allowed to prescribe Nevirapine indiscriminately or irresponsibly. That is also not what is asked. It can only be prescribed after proper testing and counseling.

Mr Marcus has indicated that he has no objection to a further qualification, along the lines of the Western Cape practice, that such prescription be done after consultation with the medical superintendent in charge of the facility concerned.

Access to Nevirapine in this manner is in my view a vital element that is lacking in the programme

of the first to nine respondents. It would add an element of flexibility and pragmatism. It will allow a capacity that hitherto has been inhibited to manifest and develop itself. It need not in any way detract from the integrity of the pilot sites and the valuable work done there. It merely provides another means of access, less structured, less perfect, but infinitely to be preferred to the choice between all or nothing.

In this respect therefore I am of the view that the policy of the first to nine respondents in prohibiting the use of Nevirapine outside the pilot sites in the public health sector is not reasonable and that it is an unjustifiable barrier to the progressive realization of the right to health care. It is a breach of their negative obligation (see **Grootboom's** case *supra* at para 34) to desist from impairing the right to health care. The breach can be remedied by relief as prayed in prayers 1 and 2, appropriately amended as suggested above.

I shall now deal with the relief claimed in paragraphs 3 to 8.

It is necessary to refer to the various pronouncements of dr Ntsaluba on what the programme of the first to nine respondents. At p 656 it is stated that the said respondents had embarked on a research and training programme before making Nevirapine available at every public health facility. At p 652 it is stated that the complete support services and products required for the effective use of Nevirapine are not fully known. It is necessary to investigate these before Nevirapine is made available at every publich site. The question of breast feeding must also be investigated in this context. At p 696 he says that it is necessary that the drug be released in controlled settings with the object of gathering as much data as possible in order to extend the programme to the greater public as resources allow. At p 698 he refers to the affidavit of dr Simelela for greater detail concerning the programme. At p 713 he says that it is the aim of the first to ninth respondents to make Nevirapine available to the general population gradually.

At p 715 he states that an incrementalist approach is to be preferred. At p 717 he says that the respondents are obliged to have a full grasp of the full requirements for a successful MTCT prevention programme before they can make Nevirapine available at all public health facilities. At p

729 he denied that there was no clear plan for a comprehensive roll out. In respect of this issue, he referred to the affidavit of dr Simelela. At p 733 he says that as information is gathered, and more is learnt about the operational challenges, it is envisaged that the programme will be rolled out to other sites. At p 734 he says that the respondents are keen to implement and deliver an integrated programme as soon as is reasonably feasible, as soon as their concerns as outlined in the first respondents letter have been sufficiently addressed. Those concerns, it will be remembered, relate to resistance and breast feeding. At p 788 he says that it is envisaged that the programme will be extended as lessons are learnt from the research and training sites and as more resources are realized. At p 808 he says that the respondents have already embarked on a carefully planned programme in all provinces aimed at providing an infrastructure for counseling and testing of affected mothers. Due to a dearth of resources it is impossible to implement it immediately in all public sector facilities.

It is sufficient to say that dr Simelela in her affidavit nowhere gave particulars of a clear plan for a comprehensive roll out. At p 1974 she says that the cost of a MTCT prevention programme has to be assessed in order to perform a progressive extension of the programme.

All this leads only to one conclusion: that there is no comprehensive and co-ordinated plan for a roll out of the MTCT prevention programme. At best the intention, even the keenness, to extend the programme to the whole population is expressed. There is no unqualified commitment to reach the rest of the population in any given time or at any given rate.

Where section 27(2) obliges the state to take reasonable measures to achieve the progressive realisation of the right to health care, I do not think, if one has regard to the fundamental rights at stake, that the steps taken by the state to give the whole affected population access to a MTCT prevention programme can be regarded as reasonable.

A programme that is open-ended and that leaves everything for the future cannot be said to be coherent, progressive and purposeful. The programme falls to be criticized for much the same considerations that were mentioned in the **Grootboom** case.

The plan of the tenth respondent has all the elements of a co-ordinated and programmatic plan. It is driven by a time scale. It allows of access outside the pilot sites. The respondents have tried to make capital of the statement of dr Abdullah that it is not possible to do detailed planning more than 12 months in advance. That may be so. If dr Abdullah is not doing detailed planning in 2001 for 2003, he knows that he will have to do that planning at some later stage so that he would be able to meet his target of 100% coverage by the end of March 2003. The programme of the respondents lacks the impetus that is required for a programme that must move progressively. If there is no time scale, there must be some other built-in impetus to maintain the momentum of progression. It must be goal driven. As stated in **Grootboom** case *supra* at p 71 there is a balance between goal and means. Sometimes the goal will enforce the creation of the means. Sometimes the attainment of the goal will be delayed for lack of means. What I find unacceptable in the respondent's' approach is the formulation that once the lessons have been learnt from the test and research sites, the roll out will follow as the means allow. That does no justice to the exigency of the case.

About one thing there must be no misunderstanding: a countrywide MTCT prevention programme is an ineluctable obligation of the State. The respondents alleged that it was unaffordable with AZT. It is clear that with Nevirapine it is affordable. That is the reason why the respondents have adopted Nevirapine as their drug of choice and launched the 18 pilot projects. To the extent that the impression was created in the affidavits filed on behalf of some of the respondents that the further roll out of the programme will depend on the availability of resources, it must be dispelled. The resources will have to be found progressively. The availability or resources can only have an influence on the pace of the extension of the programme. But there must be a plan for a further roll out. Only if there is a coherent plan will it be possible to obtain the further resources that are required for a nationwide programme, whether in the form of a reorganisation of priorities or by means of further budgetary allocations.

The provinces have given figures of their budgets, the amounts spent on HIV/AIDS, the cost of the pilot projects and the projected cost of a MTCT programme with 100% coverage. The figures show that the cost of a universal programme is not beyond the means of the provinces. Obviously universal

programmes cannot be afforded immediately. The Eastern Cape had a health budget of R3,835 billion. Of that R33 million was allocated to HIV/AIDS (and not spent). A comprehensive programme is estimated to require an extra R56,8 million. These figures show, in my view, that with proper planning, it should be possible to achieve full implementation gradually. The Free State Province estimates the cost of a full programme to be R23 million. KwaZulu Natal's estimate is R36 million or R48 million. The Northern Province's estimate is R71 million. These figures, hypothetical as they are, are not without their discrepancies. They must be contrasted with the figures of the Western Cape, which are the figures of a province actually engaged in a roll out. At present the Western Cape is rolling out its programme from 50% to 90% of the affected population. The cost will be R12 million. The cost for the year 2002 - 2003, with universal coverage in mind, is estimated at R21 million. I repeat: a MTCT prevention programme with full coverage is affordable with proper planning.

For all these reasons I have reached the conclusion that the applicants have made out a case for relief in terms of prayers 3 to 8. I shall modify the prayers slightly to make it quite clear that what is required is a plan that moves towards comprehensive coverage. Obviously there will be areas where progress can be faster. The plan must have the flexibility to allow for that.

There was no dispute that the applicants would be entitled to an order for costs, including the costs attendant upon the employment of two counsel.

I shall bear in mind that this judgment is delivered at an awkward time, just before the holiday season. I shall therefore adjust the period within which compliance is to be effected.

The following order is granted:

1 **It is declared that the first to ninth respondents are obliged to make Nevirapine available to pregnant women with HIV who give birth in the public health sector, and to their babies, in public health facilities to which the respondents' present programme for the prevention of mother-to-child**

transmission of HIV has not yet been extended, where in the judgment of the attending medical officer, acting in consultation with the medical superintendent of the facility concerned, this is medically indicated, which shall at least include that the woman concerned has been appropriately tested and counselled.

2 The first to ninth respondents are ordered to make Nevirapine available to pregnant women with HIV who give birth in the public sector, and to their babies, in public health facilites to which the respondents' present programme for the prevention of mother-to-child transmission of HIV has not yet been extended, where in the opinion of the attending medical practitioner, acting in consultation with the medical superintendent of the facility concerned, this is medically indicated, which shall at least include that the woman concerned has been appropriately tested and counselled.

3 It is declared that the respondents are under a duty forthwith to plan an effective comprehensive national programme to prevent or reduce the mother-to-child transmission of HIV, including the provision of voluntary counselling and testing, and where appropriate, Nevirapine or other appropriate medicine, and formula milk for feeding, which programme must provide for its progressive implementation to the whole of the Republic, and to implement it in a reasonable manner.

4 The respondents are ordered forthwith to plan an effective comprehensive national programme to prevent or reduce the mother-to-child transmission of HIV, including the provision of voluntary counselling and testing, and where appropriate, Nevirapine or other appropriate medicine, and formula milk for feeding, which programme must provide for its progressive implementation to the whole of the Republic, and to implement it in a reasonable manner.

5 Each of the respondents is ordered to deliver, before 31 March 2002, a report or reports which set out, under oath:

5.1 what he or she has done to implement the order in paragraph 4

5.2 what further steps he or she will take to implement the order in paragraph 4, and when he or she will take each such step.

6 The applicants may within a month of delivery of such reports deliver their replies, under oath, to the respondents' reports.

7 The respondents may within two weeks of delivery of such reports deliver their answers to the replies of the applicants.

8 The application is postponed to a date to be fixed by the registrar for the consideration and determination of the said reports, replies and answers.

9 The first to ninth respondents are ordered to pay the applicants' costs, including the costs attendant upon the employment of two counsel.

C BOTHA

JUDGE OF THE HIGH COURT