



aidslaw
project

Centre for Applied Legal Studies (CALs)
University of the Witwatersrand
Private Bag 3, Wits 2050, South Africa
C/o DX 197 Johannesburg
Tel +27 11 717-8600 • Fax +27 11 403-2341
www.law.wits.ac.za/cals/alp

**Joint submission on draft regulations to the
Medical Schemes Act 131 of 1998 (Gazette
No. 26345) dated 21 May 2004**

Treatment Action Campaign (TAC)

www.tac.org.za

AIDS Law Project (ALP)

www.alp.org.za

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Submission prepared by Fatima Hassan

Attorney, Law & Treatment Access Unit

AIDS Law Project

fatima@tac.org.za

083 27 999 62

Tel. 021 467 5673

Fax. 021 461 2814

INTRODUCTION

1. South Africa has a population of about 45 million people. In respect of health care, the private medical scheme sector serves approximately 7 million beneficiaries. It is reported that in 2003 alone, the private sector spent about 40 billion rand on health care for 7 million beneficiaries.¹
2. There are approximately 5 million people living with HIV/AIDS in South Africa.² Without appropriate treatment to prevent and/or delay the onset of AIDS, the number of AIDS related deaths is likely to increase³
3. It is within this context that the Cabinet approval of the Operational Plan for HIV /AIDS Care, Management and Treatment in November 2003 (Operational Plan) for the public sector and the proposed prescribed minimum benefit (PMB) for HIV/AIDS in the private sector are significant.⁴

MANDATE OF THE TREATMENT ACTION CAMPAIGN (TAC) AND THE AIDS LAW PROJECT (ALP)

4. The **Treatment Action Campaign** (TAC) is a voluntary association of individuals and organisations dedicated to ensuring access to affordable and quality treatment for all people with HIV/AIDS, to

¹Reported at Annual BHF Conference Cape Town June 2004.

²See ASSA Revised Model published in 2004. Also according to the 'Department of Health, 2003 National HIV and Syphilis Antenatal Sero-Prevalence Survey in South Africa: 2002' (the survey) 'HIV and STI's continue to be significant public health problems in South Africa. The number of individuals infected with HIV continues to be a cause for concern. In conclusion, the findings of the 2002 survey indicate that an estimated 5.3 million people are infected with HIV in South Africa. The full participation of all sectors of society and the strengthened intersectoral involvement in implementing the HIV/AIDS and STI strategic initiatives will be critical to an effective national programme' [at page 12].

³ There have been two studies examining death registration data to determine mortality due to AIDS. State institutions, Statistics South Africa (SSA) and the Medical Research Council (MRC), conducted both. Cabinet commissioned the SSA report. Both studies demonstrate the increased and massive mortality due to HIV. Their findings are included in a recent publication of the Health Department entitled 'Key Health Statistics 2003' where 'HIV disease' is listed among the five leading causes of death for both men and women (pages 35, 37).

⁴ **Draft regulations to the Medical Schemes Act 131 of 1998 (Gazette No. 26345) 21 May 2004**

preventing and eliminating new HIV infections, and to improving the affordability and quality of health-care access for all.

5. In July 2004, the TAC co-hosted a People's Health Summit (PHS) with a number of other organisations. One of the resolutions taken at the summit is to ensure that antiretroviral (ARV) treatment is provided as a PMB from 2005.⁵
6. The **AIDS Law Project** (ALP) is a not-for-profit organisation based at the Centre for Applied Legal Studies (CALS) at the University of the Witwatersrand, which provides free legal advice and litigation services to people who have been discriminated against on the basis of their HIV/AIDS status and to organisations working to advance the rights of people with HIV/AIDS. The ALP is a UNAIDS collaborating centre and a partner organisation of the Canadian HIV/AIDS Legal Network.

THE CONTEXT OF THE MEDICAL SCHEMES ACT

7. Section 27(2) of the Constitution imposes on the state a positive obligation to take reasonable measures to realise the right of access to health care services for all. By enacting the Medical Schemes Act, 131 of 1998 (the Act), government has created a powerful framework for the effective regulation of the private medical scheme industry.
8. By increasing access to private health care for thousands of people who were previously excluded from membership by virtue of the race, gender, age and health status, the Act makes a substantial contribution towards discharging this positive obligation. The TAC and the ALP recognise that the DoH has played a crucial role in paving the way for

⁵ Co-hosted by the Treatment Action Campaign (TAC), the Health & Other Services Personnel Trade Union of South Africa (HOSPERSA), the South African Democratic Nurses' Union (SADNU), the Public Service Accountability Monitor (PSAM), the Eastern Cape Provincial Council of Churches, the Rural Doctors Association of Southern Africa (RuDASA) and Médecins San Frontières (MSF). Adopted in the plenary session on July 4, 2004, East London, South Africa. The full text of all the resolutions is available at www.tac.org.za, newsletter 13 July 2004.

persons living with HIV/AIDS to join a medical scheme and thereby avoid being subjected to unfair discrimination.

9. The ALP supported the enactment of the Medical Schemes Bill (now the Act) on the grounds that it gave effect to section 27(1) and (2) of the Constitution.⁶ The ALP's oral and written submissions on the Bill dealt with the issue of private and public benefits in detail. TAC and the ALP remain committed to the principles of the Act: non-discrimination, increased access to health care services, prescribed minimum benefits (PMBs) and effective regulation of the private medical industry.
10. The Act guarantees beneficiaries access to a minimum standard of care through the promulgation of regulations and a list of PMBs. TAC and the ALP support the adoption and implementation of PMBs for all health conditions on the understanding that PMBs guarantee beneficiaries the right of access standard essential health care services for all health conditions
11. In our view the availability of ARV treatment for users in the public health sector means that private sector patients must also have access to the same or higher standard of benefits that include access to ARV treatment.
12. The "Explanatory Note" to the current set of PMBs recognise that frequent changes in medical practice and technologies warrant periodic changes.⁷ It unambiguously states that one of the objectives of introducing PMBs is 'to encourage improved efficiency in the allocation of Private and Public health care resources'. Calling for a review of the PMBs every two years, the Note makes it plain that such periodic reviews must 'focus specifically on the development of protocols for the

⁶ ALP Submission to the Parliamentary Portfolio Committee on Health on the Medical Schemes Bill B 116-98, 18 September 1998. Available from the ALP resource centre SeloaneM@law.wits.ac.za.

⁷ Annexure A to the Medical Schemes Act 131 of 1998 (as amended).

medical management of HIV/AIDS’, and that ‘recommendations for the revision’ will be on the basis, *inter alia*, of ‘cost effectiveness of health technologies or interventions’ and ‘consistency with developments in health policy’.

13. Significantly, the mandatory provision of ARV treatment in the private sector will in our view reduce the burden on the public sector ARV treatment programme.⁸ This is because without adequate private sector ARV treatment (mainly through medical schemes) patients will continue to be dumped on the public sector.

IMMEDIATE IMPLICATIONS OF PROPOSED PMBs FOR BENEFICIARIES – SETTING MINIMUM STANDARDS

14. In light of the proposed PMBs, which we support and welcome, beneficiaries who join on or after the regulations come into effect and who are living with HIV/AIDS, will not be subject to pre-existing illness waiting periods in so far as the treatment of HIV through the use of ARVs are concerned. Because the waiting periods do not apply to benefits guaranteed under the PMBs beneficiaries will now be better protected. This is important because:

- In the past few years, we have dealt with several cases of people living with HIV/AIDS who have had to wait up to 12 months before their respective medical scheme paid for the costs of managing and monitoring ARV treatment. In many instances this led to undue physical and financial hardship.
- Often, we found that schemes cherry picked the young and/or healthy by covertly and indirectly discouraging people living with HIV/AIDS from joining schemes. They did this by designing benefit packages that are insufficient and limited which do not cover the costs of managing and monitoring ARV treatment.

⁸ See here the first updated report on the ARV rollout presented by the TAC and ALP. 22 July 2004. Available on www.tac.org.za.

- Also, through research conducted by CARE in 2002⁹, we discovered that a number of schemes that had at that time already started providing ARV treatment, were offering substandard treatment regimens to beneficiaries. As a result, we submitted a complaint to the Council for Medical Schemes (Council) in December 2002 requesting an investigation into the provision of substandard ARV treatment as well as the adoption of standard treatment protocols for the medical schemes sector. We look forward to the findings of this investigation being made public by the Council.
- It is important to note that the CARE survey referred to above revealed that even though the current set of PMBs did not mandate ARV treatment, most schemes, nevertheless provided ARV treatment. However, in doing so, some schemes were offering substandard and dangerous treatment regimens. It is this aspect of the provision of ARV treatment by schemes that we requested the council to investigate.

15. Subsequently, and pursuant to the adoption of the Operational Plan, the Department of Health (DoH) adopted ARV Treatment Guidelines for both adults and children on 31 March 2004 in accordance with international treatment guidelines prepared by the World Health Organisation (WHO)¹⁰ and in accordance with the medical, clinical and laboratory criteria set out in the Operational Plan. Of course this does not preclude the private sector from offering different drug regimens from that, which is already being provided in the public sector. This is because while the public sector guidelines provide for first and second

⁹ *HIV/AIDS Benefits in Medical Schemes in 2002*. TAC, Centre for Actuarial Research (CARE) 2002.

¹⁰ The 2003 revised WHO treatment guidelines for ARV treatment in resource-constrained settings describe in detail the WHO recommendations for initiating ARV treatment among children, adolescents and adults living with HIV/AIDS. WHO recommends offering ARV treatment to adolescents and adults with: WHO Stage IV disease irrespective of CD4 cell count, WHO Stage III disease with consideration of using CD4 cell counts less than 350 106 cells/L to assist decision making, and WHO Stages I and II disease in the presence of a CD4 cell count less than 200 106 cells/L. In our view, the private sector in SA is by no means resource-constrained.

line treatment regimens, some beneficiaries in the private sector are on third and fourth line drug regimens.

16. We should caution that in developing any treatment protocol for the private medical scheme sector, the Council should ensure that patients that are already receiving ARV medicines that are considered part of a third or fourth line drug regimen should continue to receive them. That is, patients should not be switched to the ARV medicines that are part of the public sector first and second line drug regimens, unless of course it is medically indicated. What we are cautioning against here is the possibility of schemes switching drug regimens on the basis of what ARV medicines are being made available to public sector patients, without considering the clinical and virological impact of such a switch. Finally, we urge the Council to develop a treatment protocol for the private medical schemes sector by closely following the recently revised SAHCS treatment guidelines.

17. The national treatment guidelines for the public sector are important because they serve as a guide for what the minimum standard of care is, that is, it sets the MINIMUM criteria that must be available in the private sector.

18. While the conceptual framework of the PMBs is to oblige the private sector to guarantee and pay for medical treatment that is available in the public sector, there is nothing in the Act that precludes the PMBs from including benefits that **exceed** that which is available in the public sector- or that should be available in the public sector.

19. The exception to this rule relates to 'medical and surgical management'. The exception however does not apply to the PMBs for HIV/AIDS. The latter can therefore legally offer more than that is currently offered by the public sector and we submit that it should for the following reasons:

- The public sector programme will be implemented over time using a phased approach, unlike the immediate provision of ARV treatment that is envisaged by the PMBs -- for eligible scheme beneficiaries in the private sector.
- The number of patients that the public sector programme aims to treat over the next few years is not comparable to the substantially smaller number of beneficiaries likely to benefit from ARV treatment through the PMBs.
- It is therefore necessary and reasonable to expect the private sector to offer a benefit that exceeds that which is available in the public sector. At the very least, where the minimum benefit is available in the private sector, it will assist in cases where beneficiaries are shifted to the public sector due to for example, retrenchment, resignation or dismissal.

THE PROPOSED REGULATIONS

20. Both TAC and the ALP have campaigned for many years for the expansion of the PMBs for HIV/AIDS to include ARV treatment. We therefore welcome and support the proposed PMB for HIV/AIDS. We would like to congratulate the Council and the DoH on taking such a step which will ensure that private funded patients have access to life-saving ARV treatment.

21. In our view, the PMBs are a useful tool to ensure that all beneficiaries are guaranteed access to a minimum set of health care services. For people living with HIV/AIDS this is an important benefit. Historically, they were excluded from scheme membership. Also, once the Act came into effect, many beneficiaries who were (and still are) accessing ARV treatment, had to contribute to the costs of treatment through co-payments and by using their medical savings accounts (MSAs).

22. This additional financial burden often resulted in treatment interruption. In some cases, the very low monetary benefit available for ARV

treatment meant that only one member of a family could access ARV medicines.

23. We are therefore optimistic that the inclusion of ARV treatment as a PMB will lead to beneficiaries having uninterrupted access to ARV treatment as well as access to appropriate medical management and monitoring.

OUR SUBMISSION

24. We welcome and support the proposed expansion of the PMBs for HIV to include ARV treatment.¹¹ We support the efforts by government to ensure that both the public and private sector play their role in addressing the impact of AIDS on our country. Both sectors are jointly responsible for increasing and providing access to health care services. Obviously, where possible, we must ensure that the public sector is not overburdened.

25. However it is our view that while the proposed benefit clearly includes and contemplates as part of the benefit ongoing diagnostic and monitoring services, it needs to explicitly refer to it. In the absence of an explicit inclusion, some schemes and/or administrators may interpret the benefit in a narrow manner, which does not recognise its inclusion.

- That is, the scheme or administrator may argue that the minimum benefit does not explicitly include laboratory tests as part of the assessment process and laboratory tests for monitoring patient adherence. In such cases they will argue that they are not obliged to provide and pay for such services under

¹¹ The first set of proposed PMBs for HIV, restricted the benefit to beneficiaries with a CD4 count of 100 or less. The ALP did not support this benefit on the grounds that a “CD4 100” clinical marker was arbitrary and inappropriate. Subsequently, the wording of the PMBs was amended so that the current benefit is available to all beneficiaries living with HIV, irrespective of their CD4 count. *AIDS Law Project Submission on Draft Regulations issued in terms of the Medical Schemes Act 131 of 1998*. Available from ALP resource centre SeloaneM@law.wits.ac.za.

the PMBs and thus burden the beneficiary to bear the costs of monitoring.

We therefore propose that the benefit should explicitly mention monitoring services to avoid any potential future interpretation disputes. While the drafters of the proposed PMB must have intended to include monitoring, we feel that it is advisable to explicitly refer to monitoring in the wording.

EXISTING AND PROPOSED BENEFITS

26. At present, the PMB for HIV is:

HAEMATOLOGICAL, INFECTIOUS AND MISCELLANEOUS SYSTEMIC CONDITIONS ¹²

Code: Diagnosis: Treatment:

168S # HIV-infection #

- HIV voluntary counselling and testing
- Co-trimoxazole as preventative therapy
- Screening and preventative therapy for TB
- Diagnosis and treatment of sexually transmitted infections
- Pain management in palliative care
- Treatment of opportunistic infections
- Prevention of mother-to-child transmission of HIV
- Post-exposure prophylaxis following occupational exposure or sexual assault

27. The proposed PMB for HIV includes the following:

- *'Medical management and medication, including the provision of anti-retroviral therapy, to the extent that this is provided for in established national guidelines applicable in the public sector.'* ¹³

¹² REGULATIONS GNR.1262 of 20 October 1999: As amended by Notice Government Gazette Date R.570 21256 5 June 2000 R.650 21313 30 June 2000 R.247 23193 1 March 2002 R.1360 24007 4 November 2002 1397 25537 6 October 2003.

¹³ Amendments to the General Regulations made in terms of the Medical Schemes Act 131 of 1998 (Gazette No. 26345) dated 21 May 2004. No R. 595.

28. The proposed PMB broadens the current benefit to include ARV treatment. As mentioned before, we support and welcome the expansion of the PMBs to include ARV treatment.

29. Before we commence our discussion about the proposed benefit we should point out that according to the DoH, it has developed guidelines for *inter alia*:

- HIV testing;
- Managing HIV in children;
- Preventing MTCT;
- Occupational exposure to HIV;
- Infant feeding where the mother is HIV positive;
- Ethics in HIV research;
- Tuberculosis (TB) management and AIDS;
- Treatment of adult OIs;¹⁴
- PEP for sexual assault survivors; and
- Adult and paediatric ARV treatment (see paragraph 13 above).

30. The public sector guidelines referred to above reveal the standard of care that is intended to be available in the public sector. They also indicate the minimum standard of care for private sector patients. They do not however preclude a slightly better or optimal standard of care in the private sector.

VCT and TB and STIs

31. The nature of the “testing” that is required as part of an overall management programme is not clear nor does the proposed benefit specify the frequency with which these tests must be covered. Our previous submission dated 31 July 2002¹⁵ recommended the explicit

¹⁴ Cited in the Department of Health Annual Report 2000/2001, at p 27.

¹⁵ ‘Joint Submission on draft Amendments to the Medical Schemes Act 131 of 1998 (Gazette No. 23379) dated 30 April 2002’. TAC and ALP 31 July 2002. Available from ALP resource centre at SeloaneM@law.wits.ac.za.

inclusion of on-going counselling and monitoring of HIV infection. In this respect please see the section below on diagnosis and monitoring.

32. In our July 2002 submission we stated that although Hepatitis B is transmitted through sexual contact or contact with the bodily fluids of people who have Hepatitis B, there is no explicit provision in the proposed PMB for the prevention of Hepatitis B. We again recommend that the PMBs include the vaccination of all persons living with HIV against Hepatitis B.

Pneumocystis carinii pneumonia (PCP)

33. Current medical practices show that cotrimoxazole (trimethoprim-sulfamethoxazole), dapsone or pentamidine can be used in the treatment of PCP. In our submission of July 2002 we recommended a redrafting of the benefit to read as follows: 'prophylaxis for the prevention and/or treatment of PCP, including but not limited to cotrimoxazole, dapsone or pentamidine'.¹⁶ We repeat our recommendation.

Post Exposure Prophylaxis (PEP)

34. In our July 2002 submission we expressed concern about the lack of an explicit provision that guarantees ongoing counselling in the context of PEP.¹⁷ We therefore again recommend its inclusion.

Prevention of Mother-to-Child Transmission of HIV (PMTCT)

¹⁶ In our July 2002 submission we noted that cotrimoxazole has relatively high side effects and resistance profiles. However, HIV specialists agree that the benefits of using cotrimoxazole outweigh the risks. See Helweg-Larsen et al "Effects of mutations in *Pneumocystis carinii* dihydropyrimidinase synthase gene on outcome of AIDS-associated *P. carinii* pneumonia" The Lancet Vol 354 October 16 1999 p1347-1355.

¹⁷ In our July 2002 submission we noted that on 29 May 2002 the Minister of Health issued a statement indicating that a National Protocol for the provision of ARVs to sexual assault survivors is now in place: "*Policy Guideline for Management of Transmission of Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infections in Sexual Assault*". The policy guideline is modeled closely on the guidelines that are used for occupational exposure in the public sector: AZT 200mg 8 hourly for 28 days and 3TC 150mg 12 hourly for 28 days will be provided, preliminary testing; pre-drug counseling; follow up HIV testing; regular blood tests and drugs in syrup form for children. In other words, counselling, treatment for physical trauma, prevention of pregnancy and STIs and the compilation of forensic evidence.

35. In July 2004 the World Health Organization (WHO) published new guidelines underlining the effectiveness of ARVs to prevent MTCT. These guidelines take into account the most recent information on the safety and effectiveness of different drug regimens, as well as concerns over resistance to some of the drugs used, including nevirapine. A full copy of the guidelines is available at <http://www.who.int/mediacentre/releases/2004/pr50/en/>.¹⁸

36. The key WHO recommendations are:

- i. Women who need ARV treatment for their own health should receive it in accordance with the WHO guidelines on ARV treatment. The use of ARV treatment, when indicated, during pregnancy substantially benefits the health of the woman and decreases the risk of HIV transmission to the infant.
- ii. HIV-infected pregnant women who do not have indications for ARV treatment, or do not have access to treatment should be offered ARV prophylaxis to prevent MTCT using one of several ARV regimens known to be safe and effective.¹⁹ Therefore, for pregnant women who do not yet need or have access to ARV treatment for their own disease, the use of ARV prophylaxis for preventing MTCT is recommended.
- iii. AZT, 3TC and nevirapine are the drugs of first choice in preventing MTCT. They have been formally assessed for

¹⁸ By addressing issues of efficacy, safety, drug resistance and feasibility, the guidelines indicate ARV regimens to be included in programmes to prevent mother-to-child transmission of HIV. 'It is intended to support and facilitate antiretroviral treatment for pregnant women and women of reproductive age who have indications for treatment. The guidelines may also be useful for health service providers as specific recommendations are provided for the most frequently encountered clinical situations'.

¹⁹ Zidovudine from 28 weeks of pregnancy plus single-dose nevirapine during labour and single-dose nevirapine and one-week zidovudine for the infant. This regimen is highly efficacious, as is initiating zidovudine later in pregnancy. Alternative regimens based on zidovudine alone, short-course zidovudine + lamivudine or single-dose nevirapine alone are also recommended.

safety and efficacy in many clinical trials. Administering them is relatively simple. All three drugs can be taken twice daily, and appropriate infant formulations are available. To further simplify prophylaxis, co-formulations are available, thus reducing the number of pills to be taken. Finally, nevirapine can be used in a single-dose formulation for intrapartum use only.²⁰ The guidelines also refer to the issue of drug resistance.

37. The MCC's recent recommendation that combination therapy is more effective for PMTCT is also relevant here.²¹

38. We therefore submit, as we did in July 2002, that the proposed PMTCT benefit for the private sector should not be limited to the provision of monotherapy nevirapine, particularly given the proven efficacy of several alternative regimens that have resulted in lower transmission rates. Having said this, it is important to bear in mind that we are not advocating that nevirapine monotherapy should not continue to be provided in circumstances where it may be a necessary and lifesaving intervention.²²

39. In our view therefore, schemes should be obliged through the proposed PMB to ensure that pregnant women beneficiaries of schemes, where medically appropriate, access combination ARV therapy. The PMTCT benefit must therefore be linked with the proposed ARV benefit. In line with the WHO recommendations, where ARV treatment is not medically indicated for the pregnant woman concerned, then some other regimen must be provided through the PMB.²³

²⁰ NVP is expected to be available soon in a single-dose formulation for infant use.

²¹ See MCC Media Release dated 12 July 2004 and GCIS Statement on Cabinet Meeting dated 21 July 2004.

²² Where the mother presents late for any other option, or where it is only possible to give a double dose of nevirapine to the child post-partem.

²³ Such as short-course AZT boosted by single-dose nevirapine in labour.

40. In our submission of July 2002 we also stated that a reasonable PMTCT benefit in the private sector should include access to caesarean section, formula feed, vitamins and antibiotics for infants born to mothers living with HIV.²⁴ In that submission we explained why these were necessary and effective interventions in reducing transmission rates.
41. Also, read with the proposed ARV benefit, the proposed PMB remains unclear about whether on-going testing and counselling is included including qualitative PCR tests for infants²⁵, viral load tests and regular CD4 tests as part of an overall management and treatment programme of both mother and infant. Again, we recommend the inclusion of these tests under the PMTCT and ARV treatment benefit.
42. This is because the effective prevention of PMTCT requires a comprehensive treatment programme that is not limited to the pre-partum and intra-partum period.
43. Therefore, given the number of beneficiaries that have access to MTCT in the private sector, a standard, reasonable, highly efficient and comprehensive treatment programme is appropriate and necessary.

Opportunistic Infections (OIs)

44. Our July 2002 submission recommended that this benefit should be redrafted as follows: 'treatment of all opportunistic infections including but not limited to CMV retinitis, cryptococcal meningitis; oral,

²⁴ See the Department of Health's policy guideline on "*The PMTCT and Management of HIV positive women*", May 2000. The guideline calls for alternatives to breastfeeding to be made "available and affordable". Cited in *Minister of Health and Others v Treatment Action Campaign and Others* CCT 8/02 5 July 2002 at Para 91.

²⁵ The Operational Plan provides that infants aged below 18 months will require an HIV p24 Antigen test to determine their true HIV status. While the HIV p 24 Antigen will be used in the public sector, we propose that the PMB should oblige schemes to test babies for HIV at 6 - 10 weeks using PCR tests. The PCR test is highly specific for HIV infection, but sensitivity varies with the age of the infant. The PCR identifies approximately 50% of infected infants at or just after birth and > 95% at 3-6 months of age. See here G Sherman 'Infant HIV Diagnostic Guidelines to facilitate adoption' in SA Journal of HIV Medicine May 2003 at page 24.

oesophageal and vaginal candidiasis; Kaposi sarcoma, TB lymphoma and pneumonia'. We repeat our recommendation.

Pain management and palliative care

45. 'End of life care' has again not been included in the proposed PMB. Yet, end of life care is crucial for improving the quality of life of many people living with AIDS, and it also reduces both public and private sector hospitalisation costs. Again, we recommend its inclusion.

Monitoring

46. In our view the number and type of tests that have to be carried out for disease monitoring and treatment monitoring should be explicitly dealt with in the proposed PMB.
47. While the word 'management' in the proposed benefit must be interpreted to include clinical and laboratory monitoring as part of overall patient management, we recommend the explicit inclusion of 'monitoring' in the wording of the proposed benefit.
48. This is because the proposed PMB clearly envisages that the minimum standard of care that is available to patients in the public sector as set out in the Operational Plan and national treatment guidelines is also available to scheme beneficiaries. Both the Operational Plan and national guidelines already explicitly include monitoring services.²⁶ The proposed PMB must therefore do the same.

PUBLIC SECTOR MONITORING AS A FLOOR FOR PRIVATE SECTOR MONITORING

49. The public sector programme envisaged by the Operational Plan includes the supervision of patients through periodic visits to clinicians, nurses and counsellors and the administration of periodic CD4 and viral

²⁶ The proposed PMB: *Medical management and medication, including the provision of anti-retroviral therapy, to the extent that this is provided for in established national guidelines applicable in the public sector.* See paragraph 27 above.

load tests and other tests as necessary according to the recommended protocols (at page 17).

50. The Operational Plan recognises that regular monitoring and evaluation, both clinical and laboratory, is a critical component of the management of patients on ARV treatment irrespective of the stage of their disease. It unequivocally states that 'monitoring is needed to detect drug resistance, drug reactions, drug toxicity, drug-drug interactions as well as treatment failure and the need to either reinforce adherence or switch regimens.

51. Monitoring and evaluation is also critical to identify to eliminate potential or observed barriers to adherence. Thus, ongoing monitoring and evaluation, performed in the context of an integrated and comprehensive team approach to health care, will maximize the chance for treatment success' (at page 65).

DIAGNOSIS AND MONITORING TESTS

52. The Operational Plan specifically provides that 'a robust monitoring system will ensure an early warning system to detect drug resistant strains of the virus, adverse drug events and drug to drug interactions with other Western, traditional and complementary medicines' (at page 6).

53. The Operational Plan in its Executive Summary also 'proposes to build on testing programmes to diagnose HIV infection and measure disease progression, so that proper care and treatment regimens can be implemented' (at page 9).

54. In particular, the Operational Plan proposes baseline CD4 and viral load tests, where the indication for commencing ARV treatment is

based on a clinical assessment and a measure of the patients CD4 count.²⁷

55. In addition, 'tests to measure the patient's response to therapy, improvement in the patient's immune system, and monitoring of drug toxicity will be done where necessary and in accordance with the recommended treatment and laboratory protocols'. (at page 15)

56. The current medical and scientific consensus indicates that basic diagnosis and monitoring laboratory tests such as the Elisa test, full blood count (FBC), viral load and a CD4 count assist with identifying disease, monitoring disease progression, monitoring anemia and adverse drug events or side-effects, monitoring the overall effect of antiretroviral therapies and monitoring the immune status of the patient.

57. In particular, CD4 tests are accepted as the most appropriate and relevant marker of progression of disease. The WHO also encourages and recommends a CD4 cell count as surrogate markers in treatment programmes.²⁸

58. Monitoring a beneficiary's HIV status through regular CD4 tests assists, *inter alia*, not only in determining when ARV treatment should commence, but also in making decisions about the appropriate prophylaxis and/or treatment of OIs.²⁹ This is especially relevant where TB co-infection presents itself.

59. Recent recommendations on monitoring from the SA HIV Clinicians Society (SAHCS)³⁰ are: a CD4 baseline test on commencing treatment

²⁷ Operational Plan at page 63.

²⁸ The WHO also refers to "simple, low cost CD4 methodologies that are currently available..." *Scaling Up Antiretroviral Therapy in Resource Limited Settings Guidelines for a Public Health Approach* Executive Summary World Health Organization (WHO) Revised edition. December 2003.

²⁹ There are ongoing developments in the private pathology sector to reduce the costs of HIV related monitoring tests.

³⁰ The SAHCS met on Saturday 14 August 2004 to revise its treatment guidelines. A copy of the revised guidelines can be obtained directly from the SAHCS.

followed by a CD4 test within 6 weeks of commencing treatment and thereafter every 4-6 months. In other words, the SAHCS recommends three viral load tests and three CD4 tests per year as the minimum requirement for the management of patients on ARV treatment. The tests are necessary to identify adverse drug events, avoid resistance and toxicity and for overall disease management.

60. We therefore recommend the explicit inclusion of three CD4 tests and three viral load tests per annum in the PMB for HIV.³¹

CONSTITUTIONAL OBLIGATIONS

61. Government has a Constitutional obligation to give effect to the right of access to health care services, as entrenched in section 27 of the Constitution. In terms of section 27(2), government has a Constitutional obligation to take reasonable legislative and other measures progressively to realise the right of everyone to have the right to access health care services, including reproductive health care.

62. At minimum, government's obligations entail the creation of an enabling framework by putting in place laws and regulations so that individuals will be able to realise their rights free from interference.

63. Government has a duty progressively to realise the right of access to health care services not only in the public sector but in the private sector as well, having responsibility for the overall performance of the country's health system. This is why the Department of Health and the Council have a duty to ensure fair, reasonable and optimal HIV benefits in the private sector. As mentioned earlier in this submission, the Act goes a considerable way towards discharging such an obligation.

³¹ Viral load tests remain one of the most expensive HIV/AIDS monitoring tool.³¹ At present there are four techniques that are used to measure viral load. But patents by Roche, Organon Teknica, Bayer and Abbott on these techniques have resulted in excessive prices being charged by laboratories that use these techniques. The price has been inflated because of the increased volume of qualitative PCR tests. The initial cost of such tests was based on a low volume non-automated test process.

CONCLUSION

The TAC and the ALP support standardising treatment for HIV/AIDS through the mechanism of PMBs. We welcome the expansion of the current set of PMBs to include ARV management and treatment. Our main concern is that whilst the proposed benefit must be interpreted to include diagnosis and on going monitoring services that it need to be sufficiently explicit.

Ends ♦♦