

A sustainable HIV treatment programme requires a competitive ARV tender

Second report and resolutions of the Budget and Expenditure Monitoring Forum

February 2010

The Budget and Expenditure Monitoring Forum (BEMF), which draws together individuals and organisations from civil society, academia, government, organised labour and business, focuses attention on ensuring that sufficient money is budgeted for and appropriately spent on meeting the treatment and prevention targets of the national *HIV & AIDS and STI Strategic Plan for South Africa 2007-2011* (NSP) as well as for health more broadly. BEMF held its first meeting on 21 August 2009.

BEMF's second meeting, which was held in Johannesburg on 5 February 2010, drew together over 40 people from 19 organisations, including legal experts, clinicians, economists, government officials, epidemiologists and trade union and civil society activists. The agenda focused on the upcoming antiretroviral (ARV) drug tender and the need to ensure that it is structured and run in a manner that enables the state to procure an adequate supply of appropriate medicines at the lowest possible prices.

In particular, the meeting recognised that key to the success of the ARV treatment programme is the need to ensure that –

- government is able to procure sufficient quantities of medicines to meet demand;
- adequate funds have been budgeted;
- medicines are purchased at globally competitive prices; and
- all essential products – including appropriate paediatric formulations and fixed-dose combination pills (FDCs) – are available for procurement and use in South Africa.

For this to happen the national Department of Health (DoH) and the National Treasury must co-operate better than in the past and use the leverage they have as the world's largest ARV treatment programme, to get the best possible deals from drug companies. Insofar as the special conditions of tender are concerned, the National Treasury must take its direction from the DoH in ensuring that the particular needs of the public sector programme are appropriately addressed.

The meeting addressed several topics. Key discussion points are summarised here.

2010 ARV tender

The current ARV tender expires at the end of May 2010. Participants at the meeting were informed that the DoH, with the assistance of the Clinton Foundation Health Access Initiative (CHAI), has designed a tender process that appropriately addresses numerous issues, including the following:

- Enabling the state to purchase ARV medicines at globally competitive prices;
- Ensuring sufficient flexibility to allow companies to submit tender bids in respect of medicines that have yet to be registered for use in South Africa but in respect of which applications for registration have already been made to the Medicines Control Council (MCC); and
- Requiring companies to reduce prices in response to certain market shifts (such as significant drops in the prices of active pharmaceutical ingredients) so as to ensure that South Africa benefits from global price reductions.

The meeting was informed that draft tender documents incorporating the above flexibilities as special conditions have been submitted to the National Treasury for approval by the DoH. Importantly, it also heard that in terms of the relevant legislative framework, the DoH has the legal authority and sufficient regulatory space to determine its own special conditions of tender and the details of the process in terms of which medicine tenders are conducted.

The meeting called on the National Treasury to respond quickly and positively to the DoH's proposals, or at least to provide detailed reasons should it reject any proposal.

ARV treatment guidelines

Despite significant advances in ARV treatment, the 2004 treatment guidelines have yet to be revised. The meeting was informed of a process involving the South African National AIDS Council (SANAC) and the DoH to revise the guidelines. In calling for the most recent draft of the revised guidelines to be finalised and urgently published, the meeting recognised the need for future revisions to be guided by a transparent and well-defined process. In particular, the guidelines should be reviewed regularly to keep pace with advances in medical science. In addition, the process needs to take greater cognisance of the informed views of expert clinicians and people living with HIV.

Role of the MCC

For many reasons, the MCC has been notoriously slow and inefficient in registering medicines. Despite it having taken positive steps to address its backlog, too few ARV medicines have been registered in the past six months. This restricts the ability of the DoH to procure appropriate formulations of ARV medicines at competitive prices. In this regard, the meeting noted the need for the MCC to be allocated the necessary resources to carry out its work efficiently and effectively. In addition, it called for the MCC's staff – all employees of the DoH – to prioritise the registration of those ARV products the state seeks to procure.

Availability of generic medicines

While generic versions of many ARV medicines are currently available for use in South Africa, a number of barriers still stand in the way of key products coming to market. Key products that ought to be available in South Africa include the following:

- Cheaper generic versions of the second-line ARV drug lopinavir/ritonavir (the only protease inhibitor included in the treatment guidelines);
- Appropriate formulations of paediatric abacavir, which are still awaiting registration by the MCC; and
- FDCs covering both first and second line ARV regimens in the new guidelines.

Specifically, FDCs containing tenofovir disoproxil fumarate (TDF), lamivudine (3TC) or emtricitabine (FTC), and efavirenz (EFV), including the once-daily generic FDC manufactured by the Indian company Matrix Laboratories.

If and when registered, generic lopinavir/ritonavir products will remain unavailable in South Africa for as long as Abbott Laboratories – the patent holder – refuses to license generics companies to bring their drugs to market.

The meeting was informed that the Minister of Health is empowered by the Patents Act to compel Abbott to issue such licences on reasonable terms and recommended that he use this statutory power.

While a number of companies intend to bring generic TDF/3TC/EFV and TDF/FTC/EFV products to market, an exclusive supply and distribution agreement between Matrix and Aspen Pharmacare appears to prevent Matrix from bringing its versions – both of which have already been approved by the US Food & Drug Administration – to market in South Africa.

The meeting called on Aspen to clarify the terms and conditions of its agreement with Matrix and take all reasonable steps to ensure Aspen or Matrix brings these products to market in South Africa and submits both products for the ARV tender.

Monitoring and evaluation of the treatment and prevention programmes

The DoH has yet to implement an effective monitoring and evaluation system of its HIV treatment and prevention programmes. If and when done, this will enable it to report – with reasonable accuracy – on the following:

- Number of people initiated on ARV treatment;
- Number of people currently on treatment, including the number on second-line regimens;
- Baseline CD4 counts;
- The number of pregnant women at the various stages of the prevention of mother-to-child transmission of HIV (PMTCT) programme; and
- Number of infants tested and HIV prevalence amongst infants tested.

The meeting heard how this data should be broken down per district per quarter. In particular, it noted the importance of accurate data on what is happening in the treatment and prevention programmes to enable the development of accurate budgets and ensure appropriate forecasting to underpin procurement.

Occupational Specific Dispensation and financial management crises

The meeting was informed that the Eastern Cape Health Department does not have the funds to pay the Occupational Specific Dispensation (OSD) to eligible health care workers. This confirms months of speculation that the OSD was not properly costed and concerns that there are insufficient funds for implementation.

In addition, the DoH has already announced that new OSD packages for medical practitioners, pharmacists and some emergency personnel will be implemented from 1 April 2010.

Participants noted the urgent need for a proper calculation of the cost of the OSD packages to be made, as well as the obligations of the National Treasury and provincial treasuries collectively to ensure health departments are adequately funded to implement all health worker OSDs.

The OSD crisis emphasises the need for the public release of the Integrated Support Team (IST) reports on the financial and administrative management capacity of the DoH and provincial health departments. Commissioned by Barbara Hogan during her tenure as Minister of Health in 2008/9, the IST reports have yet to be made public. A leaked copy of the Free State report reveals startling findings about the lack of cohesion between policy and budgets, poor monitoring and evaluation, challenges to the sustainability of the ARV treatment programme and a host of other financial management problems. It is available at <http://www.tac.org.za/community/files/bemf/FreeStateIST.pdf>.

The meeting recognised the need of civil society organisations to gain access to the IST reports – not only in the interests of open and transparent governance, but also to place such organisations in a better position to assist the state to implement a better health service. The meeting thus called on Minister Aaron Motsoaledi to release these reports publicly.

Role of Parliament in the budgeting process

The Money Bills Amendment Procedure and Related Matters Act 9 of 2009, which was assented to by former President Motlanthe and came into effect on 14 April 2009, gives Parliament wider powers over the budget process and outcome. No longer is Parliament confined to being able only to vote for or against the Budget. It now has the authority and statutory obligation, amongst other things, to consider the fiscal framework, the Division of Revenue Bill and the Appropriations Bill, and to make amendments were deemed appropriate and hold public hearings on all three.

The meeting noted, however, that Act 9 of 2009 has yet to be properly implemented. In this regard, participants called for its full implementation and committed to support Parliament in this regard.

Update on the Free State

The Free State AIDS Coalition briefed participants on ongoing concerns relating to ARV treatment access in that province. While the first BEMF meeting had been informed of shortages of ARV medicines in Free State health facilities, this second meeting heard about facilities that have adequate stocks of ARV medicines but are short-stocked on a range of other essential drugs.

The meeting therefore called on the DoH to intervene in the affairs of the Free State Health Department in the manner contemplated by the Constitution.

Drug stockouts

The meeting also heard that the AIDS Law Project (ALP) and Health-e News Service have established a database to record incidents of drug shortages and other problems pertaining to the HIV treatment and prevention programmes. Any similar incidents should be reported to the ALP's Agnieszka Wlodarski on 011 356 4100 or wlodarskia@alp.org.za.

Meeting presentations and documents

Four formal presentations were made at the meeting. These are available at <http://www.tac.org.za/community/bemf#meeting-2>:

- **Nathan Geffen** of the ALP described challenges to optimising the ARV treatment rollout.
- **Francois Venter**, President of the Southern African HIV Clinicians Society, explained the new draft ARV treatment guidelines, including their advantages and shortcomings.
- **Jonathan Berger** of the ALP explained the legislative framework for public procurement, with particular reference to the 2010 ARV tender.
- **Vishal Brijlal** of the Clinton Health Access Initiative, who is advising the DoH on the 2010 ARV tender, explained the proposed tender process.

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