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Include fixed-dose combinations in new ARV tender

TAC and MSF call for the inclusion of fixed-dose antiretroviral combinations purchased at reasonable prices in South Africa?s new ARV tender

When more than one medicine is combined into a single tablet it is called a fixed-dose combination (FDC). Today most tuberculosis (TB) patients in the public sector in South Africa take FDCs, which combine into a single tablet up to four medicines active against drug-susceptible TB.

There are also FDCs of many antiretroviral (ARV) regimens, however our public sector does not yet offer them. South Africa?s upcoming ARV tender ? expected to cover the period from the start of 2013 to the end of 2014 ? is an opportunity to phase out multi-pill ARV regimens in favour of FDCs.

Antiretroviral FDCs combining tenofovir (TDF), emtricitabine (FTC) and efavirenz (EFV) into a single tablet have been available in the United States since 2006. The combinations were initially brought to market jointly by the patent holders of the originator medicines. Today there are a number of generic versions of this combination and FDCs of TDF/ lamivudine (3TC)/EFV are available globally.

Under South Africa?s updated treatment guidelines, most patients on first-line ARV regimens should now be receiving a combination of either TDF, 3TC and EFV or, TDF, FTC and EFV. The Department of Health currently procures these regimens as separate medicines through a two-year tender that was awarded in December 2010.

Why we need FDCs in the public sector

Patients will benefit more from FDCs because they simplify treatment, cutting down the number of tablets that a person has to take daily. They also allow patients to take their medication more discreetly if that is what they prefer to do. With one-pill-a-day FDCs, adhering to your antiretroviral therapy is as simple as taking daily birth control tablets.

Furthermore, FDCs improve treatment adherence. This has been established through a number of studies that have tracked adherence. An analysis of nine studies tracked the adherence of 20,242 patients - 11,925 patients on fixed-dose combinations and 8,317 patients on free-drug combination regimens (multiple drug regimens) - over an average of 8.6 months. The analysis showed that the risk of non-compliance is reduced by 26% [95% CI, P <.0001] for patients on FDCs.[1]

The benefits of FDCs extend beyond patients to health workers and health systems. FDCs make prescribing, dispensing and monitoring treatment easier for nurses and pharmacists. Also, widespread use of FDCs makes ordering and monitoring ARV stocks simpler for clinics, medicine depots and government. This is critical given the ongoing stockouts of ARVs that we have seen during the current tender period.

Furthermore, the majority of countries in the region including neighboring Lesotho, Swaziland, Botswana and Mozambique provide fixed dose combination ARVs in the public sector. SADC member states have signed regional and global agreements committing to the regional harmonization of HIV treatment protocols and policies, and South Africa?s provision of FDC ARVs will prove essential for the success of this initiative.

But despite the obvious benefits of FDCs to patients, health workers and health systems, they are still not available in the public sector. In the past such holdups have been due to delays in registration with the Medicines Control Council (MCC) and high cost.

Before the finalisation of the 2011-2012 ARV tender, TAC and partner organisations called on the MCC to fast track the registration of FDCs so that South Africa could obtain them for use in the public sector. However, the FDCs were not registered in time and remain unavailable.

The current tender will end in December 2012 and today a number of FDCs have been registered by the MCC:
- Merck Sharp & Dohme (MSD)has registered TDF/FTC/EFV FDCs. MSD sells this combination in the private sector at R483.78 for one month?s supply.
- Aspen Pharmacare has registered TDF/FTC/EFV FDCs. Aspen markets this combination in the private sector at R435.4 for one month?s supply.
- CIPLA-Medpro has registered TDF/FTC/EFV FDCs. CIPLA markets this combination in the private sector for R421.8 for one month?s supply.
- Mylan has now registered TDF/FTC/EFV and TDF/3TC/EFV FDCs. These products are however not available through the private sector.

The new tender provides the perfect opportunity to replace multi-pill regimens with FDCs. Yet, in order to begin phasing out multi-pill regimens in favour of FDCs, South Africa needs pharmaceutical companies to offer significantly lower prices for these products.

The Department of Health currently procures a month?s supply of TDF + 3TC + EFV, as separate tablets, for R113.5 ? far below the price of comparable FDCs in the private sector.

Encouragingly, Mylan has now registered FDCs for sale in South Africa. While the company has not begun marketing these products locally, internationally Mylan sells one month?s supply of TDF/FTC/EFV FDCs for R136.41 and TDF/3TC/EFV FDCs for R118.74. Given that South Africa is the largest market for ARVs globally, other companies should match or beat Mylan?s prices.

However, we note with concern that even though Mylan produces the lowest cost antiretroviral FDCs internationally, we cannot access these in the upcoming tender because of a deal between Aspen and Mylan which prevents Mylan from selling these medicines in South Africa up until 2016. This agreement is likely unlawful in terms of South African competition law. These restrictions should urgently be dissolved, in order to ensure that these low cost medicines are not blocked from South African patients.

Currently an estimated 1.5 million people in South Africa receive ARV treatment through the public sector. This number will continue to rise in the coming years as more people become eligible for treatment, with the South African government committing to put 3 million people on treatment by 2015.[2] The vast majority of patients on ART through the public sector use first-line treatment.

We call on tendering companies to:
- offer significantly lower prices for FDCs, that are comparable with multi-pill regimens prices per month.

We call on Aspen and Mylan to:
- immediately dissolve any agreements blocking the sale of affordable FDCs within South Africa.

We call on the MCC to:
- ensure that the registration of any outstanding dossiers for these medicines at the MCC are urgently fast-tracked.
We call on the Department of Health to:
- ensure that antiretroviral FDCs are included in the new ARV tender; and,

- secure prices comparable to those offered internationally.

[1] S. Bangalore et al., ?Fixed-Dose Combinations Improve Medication Compliance: A Meta-Analysis?, The American Journal of Medicine (2007) 120, 713-719
[2] South African National AIDS Council. Resolution of the South African National AIDS Council (SANAC) Sector Leaders Forum held on May 17 2011 Regarding the South Africa Country Position in Negotiations for the United Nations High Level Meeting (HLM) ?2011 Declaration on HIV/AIDS?

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