zidovudine and nevirapine. It is a highly effective and widely used 3-in-1 combination, but unfortunately not available in South Africa as Aspen appears not yet to have applied for its registration with the Medicines Control Council (MCC).

When Aspen was asked in September 2006 whether it has applied to the MCC for registration of the generic combination of lamivudine, zidovudine and nevirapine, Gavin Wiggill, Product Manager for Aspen, provided an evasive equivocal statement from which it was unclear whether they had applied. If not, it is imperative that they do so immediately.

Research indicates that stavudine, used as part of the standard first-line regimen in the Department of Health's HIV treatment guidelines, should be replaced by tenofovir, which is a potent, safe and well-tolerated ARV. Stavudine-related toxicity is one of the main reasons for discontinuation and/or changing the first-line regimen.

Few people on ARV treatment are accessing tenofovir in terms of the Medicines and Related Substances Act, as it is a time-consuming and onerous process to initiate that has to be reviewed every 6 months. Tenofovir is therefore effectively not available for treatment in public health clinics.

Both Gilead and Aspen pharmaceutical companies have applied for registration of tenofovir over the past few years but the MCC has yet to approve its registration, in spite of Aspen requesting fast-track review status for its registration in November 2005. On 24 September 2006 Aspen supplied additional information on tenofovir requested by the MCC, which has since indicated that tenofovir may possibly be registered by early 2007.

In a recent issue of the *Sunday Times*[1] Mandisa Hela, the MCC registrar, admitted that there is a drug registration backlog, with an average registration time of between 2 and 3 years for new drugs (including ARVs) entering the South African market. Experts working for the MCC indicate that this is largely owing to the exodus of skilled staff and increasing numbers of new drug applications. Reviews and evaluations of new drugs for registration are mostly outsourced to busy academics. The MCC therefore appears to be badly resourced and unable to cope with its mandate. Hela claimed that applications for registration of ARVs were automatically fast-tracked, but declined to comment on the pending tenofovir application saying 'that is confidential information'.

The MCC should review new drugs that are fast-tracked by first checking if the FDA and European Union (EU) have approved them. If so, the MCC should only check if there are any issues specific to South Africa that merit concern and then immediately register them. Atripla was approved in less than 3 months in the USA under the FDA's fast-track programme, and was made available within days following its approval. In spite of this good news about the availability of Atripla in the USA, it may take a long time before it becomes available in South Africa given the tardiness of the MCC in registering new medications, including ARVs.

Given the extent of the HIV/AIDS pandemic in South Africa, it is essential that the MCC facilitate the registration of these life-extending medications as rapidly as possible. The MCC should encourage pharmaceutical companies to apply for the registration of new ARVs as soon as they become available and ensure that the fast-track registration process is significantly improved to make these life-extending medications available much sooner.

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Child abuse and our society

To the Editor: What do we as society do to combat the threat of trauma, crime and violence? Approximately half our population are children, the most vulnerable members of society. Physical, emotional and sexual abuse among the latter has reached epidemic proportions, with approximately 25 000 sexual offences reported to the South African Police each year. Since approximately only 1 in 9 rapes are reported to the police we can assume that the annual number of sexually abused children is around 225 000. Over the last 10 years we at Red Cross War Memorial Children's Hospital have treated approximately 1 000 children under 12 years of age for rape.

What factors in our society contribute to this crime against our children?

1. The perpetrator is usually not a sinister stranger, but rather a well-known friend, family member or breadwinner.[1]

2. In nearly all rape cases, there are important power roles. The perpetrator often has considerable physical, emotional, social or economic power over the victim, making sexual assault much more likely, especially since in 99% of all cases the perpetrator is male. These factors make it very difficult for the victim to disclose or report the crime. Nearly all sexually abused children do not disclose because they have been threatened, often with death.

3. Disclosure of the sexual abuse causes significant distress for the child and his/her family, and disrupts the home environment. Medical examination, hospital admission, contact with social workers and medical staff, antiretroviral therapy and policemen investigating the assault are all major disruptive forces for any rape victim, in particular in the life of a young child. The family often takes enormous strain trying to stay together and not disintegrate.

4. South African society still has archaic and paternalistic patterns. The legal system appears to be failing the victims of sexual abuse. Adults must take responsibility for not using children and adolescents to satisfy their own needs.

5. Sexual crimes are endemic in South Africa and it is not uncommon for women to have experienced multiple rapes before they reach adulthood. Have we become so desensitised that even in the legal proceedings sexual abuse is accepted as the norm?

We urge government to finalise the New Sexual Offences Bill. It redefines rape to include male victims and penetration of body orifices with non-sexual organs. It also sets the age of consent for all forms of sexual activity at 16 years for boys and girls. Children under the age of 12 are confirmed to be incapable of consenting to sex, but the Bill includes a qualified decriminalisation of sexual experimentation where this occurs between children aged 12 - 15 years, provided that the difference in age is not more than 2 years.

It is widely acknowledged that a 'cycle of abuse' exists. A main factor in becoming a child sexual perpetrator is having been sexually abused as a child. Therefore the apparent increase in number of sexual assaults on children is of even greater concern, as this is likely to drive a cycle of ever-increasing abuse.

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The South African Hypertension Guideline 2006 is evidence-based and not cost-effective – a rebuttal

To the Editor: Gaziano[1] criticises the South African Hypertension (SAH) Guideline 2006[2] for being evidence-based but not cost-effective. He argues that global cardiovascular (CVS) risk assessment is important in making informative cost-effective treatment decisions. He gives examples that cost of treatment may range from US$20 000 per life-year saved to US$2 000 000, depending on the underlying global CVS risk. He argues that the SAH Guideline is too imprecise to assess CVS risk, and that patients at high risk may be denied treatment and patients at low risk may be treated inappropriately. For example, Gaziano argues that a patient with blood pressure (BP) below 140/90 mmHg may have an absolute risk between 1% and 25%, which is too large to make effective decisions. Additionally, a significant amount of information can be lost by creating a change from one risk category to the next by the presence of 1 - 2 major risk factors, many of which are dichoctomised.

It is very unfortunate that the *SAMJ* did not give the SAH Guideline Committee the opportunity to respond to Gaziano's criticism in the same issue of the journal. The Committee gave considerable thought to both cost-effective and evidence-based guidelines. There was complete agreement that a CVS risk-assessment strategy should be adopted to optimise resources to patients at higher risk. However, there was considerable debate with regard to whether the Committee should adopt the global CVS risk assessment or an absolute risk assessment. It was decided to base our policy on the absolute risk table of the ESH/ESC guidelines,[3] mainly for practical reasons of implementation in the primary care setting. Gaziano himself states that '*Guidelines must focus on the* ***absolute or global clinical risk*** *instead of the individual risk factors approaches in order to achieve an overall cost-effective reduction of disease.*'[1]

Gaziano is indeed correct that the actual absolute risks are not stated in the Guideline, and this is an omission. Low, medium, high and very high risk give an absolute risk of CVS event in the next 10 years of < 15%, 15 - 20%, 20 - 30% and > 30% based on Framingham data, and absolute risk of CVS death of < 4%, 4 - 5%, 5 - 8%, and > 8% based on the SCORE charts respectively.[3]

Gaziano suggests that a 45-year-old male with no risk factors has a 2% chance of developing a CVS event in the next 10 years and will ultimately require therapy according to the SAH Guideline, whereas a 55-year-old smoker with a low-density lipoprotein/high-density lipoprotein (LDL/HDL) cholesterol ratio of 6, and BP 139/84 mmHg, would not be treated according to the Guideline because he is at low risk, whereas his actual risk is 25% in the next 10 years. Let us examine these examples more carefully.

The first patient is clearly at low CVS risk, and there is agreement between Gaziano and the SAH risk table. The SAH Guideline recommends that the patient undergo lifestyle changes for the next 6 - 12 months and then requires drug treatment if the BP level remains above 140/90 mmHg. Gaziano is at issue with this policy as it is not cost-effective. It is purely speculative whether this patient will indeed require drug treatment. Most clinicians recognise that this patient is most likely to have white-coat hypertension because of the lack of risk factors and target organ damage. Repeated monitoring, which results in habituation to BP measurement, or self- or ambulatory BP monitoring, may reveal a quite normal BP profile in time. Additionally, lifestyle changes may also be helpful. Furthermore, if BP is still not controlled after 12 months, this patient is likely to be treated with a low-dose thiazide plus angiotensin-converting enzyme (ACE) inhibitor. The current cost in the state sector is R3.33 per month. Based on the risk table published by Gaziano,[1] the number needed to treat for 10 years to prevent 1 event is 33 and the direct drug