DA calls for executive interference in internal processes of independent organ of state

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Created *2011/11/28 - 12:00am*
28 November, 2011 - 00:00 ? moderator

TAC/SECTION27 statement

28 November 2011

On 27 November 2011, Marian Shinn ? the DA spokesperson on science and technology ? issued a press release entitled ?Zuma must fast track approval for HIV/Aids gel?. In accusing the Medicines Control Council (MCC) of subjecting the Centre for the AIDS Programme of Research in South Africa (CAPRISA) ?to a bureaucratic ping-pong match?, Shinn raised concerns about alleged delays in the approval of CAPRISA?s proposed clinical trial (CAPRISA 008).

Shinn claimed that ?he MCC?s indifference to the life-threatening threats of HIV infection is an act of violence against millions of women who want to take control of their sexual health through the use of this gel.? It appears from the press release that Shinn relied solely on information provided by CAPRISA. The MCC was never given the right to respond; instead responses were sought from two Ministers, neither of whom has the right to speak on behalf of the MCC.

CAPRISA 008 is an important study. Its primary aim is to assess the feasibility and effectiveness of providing tenofovir gel in a family planning clinic setting. It is designed to follow CAPRISA 004, which showed that 1% tenofovir gel reduced the risk of HIV infection in women by 39%. After nearly two decades of research, CAPRISA 004 was the first clinical trial to show that a vaginal microbicide could provide a safe and effective way to prevent sexual transmission of HIV.

We do not wish to pass judgment on either the MCC or CAPRISA. We understand that there are substantive issues that must be resolved before approval for this important trial can be granted. That said, it is important to recognize that CAPRISA 008 is not designed as a pivotal study to enable the gel?s registration, as Shinn has implied. The FACTS 001 study, which is closely modeled on CAPRISA 004, is designed to achieve that goal. It has been approved by the MCC and is already recruiting trial participants.

Of great concern, however, are Shinn?s demands. In reference to the imminent launch of the National Strategic Plan for HIV & AIDS, STIs and TB, 2012-2016, she calls for the plan ?to ensure that a world-renowned HIV preventative field trial gets approval?. She goes further: ?The Cabinet must take action to help stop this farcical process. ???Cabinet must redress the silence of its past and instruct the MCC to stop its delaying tactics in its approval of the CAPRISA 008 field trial.?

The Medicines and Related Substances Act 101 of 1965 regulates the registration, control and use of medicines and related substances intended for humans and animals. To do so, it provides in section 2 for the establishment of the MCC as a juristic person. Amongst other things, the MCC has the power to authorise and regulate the conduct of clinical trails. While the MCC must always act in accordance with its statutory mandate and the Constitution, it cannot be told what to do by the Executive.

The DA statement is particularly unfortunate because it comes a day after the announcement that the tenofovir gel arm in the VOICE trial was terminated because it was no more effective than the placebo. While there might still be a future for tenofovir gel, this trial result will require that further research proceeds with caution after a careful analysis of all the data.

We call on Cabinet to respect and protect the MCC?s independence. We further call on the MCC and CAPRISA to engage with each other in good faith, with the public interest foremost in mind. Should CAPRISA feel aggrieved by any decision of the MCC, it has lawful options at its disposal to seek relief: either before an appeal committee established by the Minister of Health or in the High Court. The DA?s calls for unlawful action should simply be ignored. Respect for the rule of law demands no less.
