



REPUBLIC OF ZAMBIA

MINISTRY OF HIGHER EDUCATION

MINISTERIAL STATEMENT TO PARLIAMENT

On

THE SONDASHI FORMULA

(SF2000)

Presented

BY

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Mr Speaker,

I thank you for the opportunity to make this statement to the House. I wish to inform this August House on the work which my Ministry is undertaking, in conjunction with other stakeholders, in the herbal area of research.

Mr. Speaker,

I wish to bring to the attention of this House the important news on the development of the Sondashi Formula. I also wish to inform this August House that the research and development of the Sondashi Formula has continued, despite some public perception that the Government had abandoned the research work.

Mr. Speaker,

In the Year 2000, Dr. Sondashi made the announcement that he had “discovered a cure for HIV/AIDS,” In 2008, the Government, through the then Ministry of Science, Technology and Vocational Training, availed funds for the research and development of the Formula. The evaluation, led by the late Dr. Patrick Chikusu, may his soul rest in eternal peace, showed encouraging signs, but was scientifically inconclusive. Dr. Sondashi, the innovator, engaged the Council for Scientific and Industrial Research (CSIR) of South Africa, and NEPAD/SANBio to validate his observations that the Formula “cured” HIV/AIDS.

NEPAD/SANBio then adopted the Sondashi Formula as its flagship project for research in herbal medicines under the Indigenous Knowledge Systems (IKS). This research was under the stewardship of CSIR which was the IKS Node. By October 2010, NEPAD/SANBio had completed investigations covering the chemistry of the potential active ingredients in the Formula, the laboratory-based efficacy (whether the medicine actually works) and toxicology (safety of the medicine – whether it is poisonous to the user) studies. They then handed over a dossier of the results to the then Ministry of Science, Technology and Vocational Training (MSTVT) of the Republic of Zambia. Based on the encouraging observations from the laboratory investigations carried out under NEPAD/SANBio, Zambia was required to carry the mantle further by conducting two critical studies sequentially. These were:

- (a) The Human Safety Trial and
- (b) The Efficacy in Humans Trial.

Mr. Speaker

In order to move the research work forward, the Ministry appointed a Steering Committee, which comprised of NEPAD/SANBio, the National Institute for Scientific and Industrial Research, and the CSIR.

The other Zambian institutions in the Steering Committee were:

1. The Tropical Diseases Research Centre (TDRC);
2. The University of Zambia (UNZA);
3. The National HIV/AIDS/STI/TB Council (NAC);
4. The Directorate of Disease Surveillance, Control and Research (DSCR) of the Ministry of Health (DSCR);
5. The Zambia Medicines Regulatory Authority (ZAMRA);
6. The National Science and Technology Council (NSTC); and
7. The Directorate of Science and Technology, Ministry of Higher Education (DST).

This team was selected to represent the multi-sectoral nature of the research. There was need for the team to always keep in mind the end product of the research, hence the involvement of all parties at the beginning of the research.

Mr. Speaker

It might seem disheartening that five years later the Safety Trial which was supposed to be the first of the two trials is yet to be carried out. I wish to inform the House that several factors impeded progress of the project. Major among these factors were:

1. An Intellectual Property Rights (IPR) dispute which was only resolved in 2012. The main issue was how to share the intellectual property amongst the many players. This is still a contentious issue in research and development work, especially in the research work that is funded with public financing.
2. Delay in the manufacture/production of capsules for the trial. The consortium partner, Medical Research Council of South Africa, who had the capability to process crude SF2000 and place the processed material into capsules, had pulled out. This was after the NEPAD/SanBio project came to an end.
3. My Ministry only released K800,000.00 against an actual clinical trial budget of K2,400,000.00. This created some difficulties in trying to readjust the original budget.
4. Failure to find a Good Manufacturing Practices (GMP) certified facility to produce the capsules at an affordable price.

Mr. Speaker

Despite these huddles, I am pleased that we have managed to overcome most of them and are now ready to conduct the first of the two trials, which is the Safety Trial.

The South African company, Afriplex, has processed and produced 23,000 capsules of the SF2000 required for the trials.

May I take this opportunity to inform the Zambian people that the trial we are about to commence is only a Safety Trial, and that this trial is not designed to confirm whether the Sondashi Formula works against the HIV virus in humans or not. This trial will be done on healthy males, who are participating in this trial on voluntarily basis. The confidentiality and safety of our participants is of paramount importance to all of us involved in this research work.

The second trial, which the Scientists call an Efficacy Trial, will be carried out later. This is the trial which will tell us, scientifically, whether the Sondashi Formula works in humans or not.

Mr. Speaker

I wish to assure the Zambian people that the Ministry of Higher Education and the Ministry of Health are committed to ensuring that the trials are carried out.

In support of this research, my Ministry has acquired pilot-scale equipment for filling and polishing capsules for the National Institute for Scientific and Industrial Research (NISIR).

The equipment will soon be installed and commissioned. We shall, thus, be able to produce capsules for research within the country.

This will definitely reduce the cost in doing health-related research. My Ministry and the Ministry of Health will work together to acquire any other pieces of equipment or machinery that our Scientists will require to establish a complete pilot production line for herbal medicines such as the Sondashi Formula.

Mr. Speaker

May I finally pledge my Government's support for Science, Technology, and Research. We are alive to the fact that without Science and Technology, our country is unlikely to develop in a manner we want it to. It is our intention to work with all stakeholders in the advancement of science, technology and research, and to ensure that the result of our research is the advancement of the social and economic status of all Zambians, and humanity at large.

I THANK YOU MR. SPEAKER