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**AFFIDAVIT**

**COMPLAINT AGAINST ZEBLON GWALA FOR BREACHING THE MEDICINES ACT  
LODGED WITH THE MEDICINES CONTROL COUNCIL AND THE LAW  
ENFORCEMENT UNIT OF THE DEPARTMENT OF HEALTH**

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I, the undersigned

**NOKHWEZI GETRUDE HOBOYI**

hereby make affirm and state as follows:

1. I am a researcher for the Treatment Action Campaign (TAC), a Section 21 company located on the third floor of 122 Longmarket Street, Cape Town. I can be contacted on 021 422 1700 or nokhwezi@tac.org.za.
2. The facts set out in this affidavit are true and correct and are within my own knowledge unless I state otherwise or the context indicates otherwise.
3. On behalf of TAC I wish to lodge a complaint against Mr Zeblon Gwala of shop no. 16, 79 Crampton Street Pinetown, Kwazulu-Natal.
4. There is evidence that Mr Gwala has acted illegally by breaching the Medicines and Related Substances Control Act 101 of 1965 as Amended (Medicines Act) as follows:

- 4.1. Mr Gwala has sold, and continues to sell an unregistered medicine that is eligible for registration, called Ubhejane, for the treatment of HIV/AIDS.
- 4.2. Mr Gwala sells Ubhejane in unlabelled bottles.
- 4.3. Mr Gwala has made false and misleading claims about Ubhejane in at least one newspaper advertisement.

#### **DESCRIPTION OF EVIDENCE**

5. Attached as annexure NK1 is a translated transcript of a video filmed by Community Health Media Trust.
  - 5.1. The transcript was carried out by Folio Translations Consultants under the guidance of Simon Hill, Project Manager, Folio Translations, Unit 2, 10 Pepper Street, Cape Town 8001, South Africa.  
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Email [projects@foliotranslations.com](mailto:projects@foliotranslations.com).  
Website: [www.folio-online.co.za](http://www.folio-online.co.za).
  - 5.2. The translation was carried out by Thandiwe Nxumalo from African Voices, No 3 Arthur Road, Muizenberg, 7945, RSA.  
Phone +27 21 7883954, Fax +27 21 7883940. Email [avoice@iafrica.com](mailto:avoice@iafrica.com).
  - 5.3. The video was filmed by Mr Mike Rautenbach of Community Health Media Trust. His telephone number is 072 486 4100.
6. I have also enclosed a copy of the video on CD.

7. I have watched the aforementioned video. Although Xhosa is my first language, I speak and understand Zulu fluently. I have also read the attached transcripts.
8. On 19 June 2006 the Community Health Media Trust film crew, consisting of Mr Michael Rautenbach, Mr Themba Baleni, Mr Peter Baker and Ms Phumzile Cobongela went to Mr Gwala's retail premises at shop no. 16, 79 Crampton Street, Pinetown.
9. They introduced themselves to Mr Gwala who gave written consent for them to film.
10. For the purpose of enquiry Ms Cobongela posed as a potential customer while Mr Baker (camera) and Mr Baleni (sound) filmed her talking to a member of Mr Gwala's staff. Mr Rautenbeuch then interviewed Mr Gwala.
11. On 20 June 2006 the same people went to Mr Gwala's factory, again with permission, and filmed part of the manufacturing process of Ubhejane.
12. It is the product of this filming that constitutes the included video and the content of the attached transcripts.
13. In the video Mr Gwala's staff instruct Ms Cobongela on how to take the medication Ubhejane for her HIV infection. She is told: "When you begin you get two 2-litres bottles. This one with a white lid boosts the immune system. This one with a blue lid fights the virus or whatever disease you have."
14. Ms Cobongela is instructed to continue with the medication for 4 months, after which time it is implied that her HIV status will change: "You will carry on drinking from the blue bottle because we will be focusing on fighting the disease or the

virus in your body. You will carry on drinking from the blue bottle for four months. After four months you can go to a doctor and check whether or not you still have the disease that you had been treated for.” This is reiterated when the seller says “You drink Ubhejane not for the rest of your life but to treat the disease. You will drink Ubhejane to treat the disease and when the disease is gone (you are healed) you will then stop and not carry on with the treatment.”

15. The video also shows that when Ms Cobongela asked whether she should take antiretrovirals (ARVs) she was told “Ok, the ARV treatment- we ask that you should not mix it with Ubhejane...[Cellular rings]... If you have started with Ubhejane, we request that you use just Ubhejane”.
16. Later on in the video Mr Gwala says “So I will not be able to comment about ARVs. But what I do know is that my patients do not mix Ubhejane with ARVs. Because there is no study that has been done to monitor people who have combined the treatments of Ubhejane and ARVs. I always say that a person should make a choice. She or he should take ARVs and not take Ubhejane. And that they should take Ubhejane if they have not started with the ARVs.”
17. Mr Gwala is therefore marketing Ubhejane as an alternative to antiretrovirals for the purpose of treating HIV. At present antiretrovirals are registered by the Medicines Control Council for treating HIV.

### **SELLING UNREGISTERED MEDICINES**

18. I am advised that Section 14 of the Medicines Act prohibits the sale of medicines that are eligible for registration with the Medicines Control Council (MCC) but which have not been registered.

19. Section 14 of the Medicines Act is titled “Prohibition on the sale of medicines which are subject to registration and are not registered”. It states “Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.”
20. The Medicines Act defines “medicine” as “any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-  
(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine;”
21. The claim made by the seller of Ubhejane in the video: “ You will drink Ubhejane to treat the disease and when the disease is gone (you are healed) you will then stop and not carry on with the treatment” classifies Ubhejane as a medicine in terms of the Medicines Act.
22. Ubhejane is not registered with the MCC.
23. I am advised that medicines for which antiviral affects are claimed are eligible for registration with the MCC.
24. I attach a copy of Government Notice No 2025 pp1-14 published in Government Gazette 1916 on 15 Dec 1967 as annexure NK2. This details drug types subject to registration with the MCC.
25. Page 4 of this notice contains drug classification 20 ‘Antimicrobial agents’ and under this heading ‘20.2.8. Antiviral agents’.

26. I am advised that regulation 6 of this notice states that the regulations of the Drugs Control Act 1965 only apply to drugs in the pharmacological classification 20 already available at the time of the regulations or immediately prior to the promulgation of the regulations.
27. However, I am further advised that Government Notice 1171 published in the Government Gazette 2117 in July 1968, attached as annexure NK3, extends the scope of the regulations by stating that any drugs in the pharmacological classification 20 that do not fall within the terms of regulation six of Notice 2025 are subject to registration under the Drugs Control Act 1965.
28. The claim that a medicine treats or cures HIV renders it an antiviral. In the video the seller of Ubhejane explains to Ms Cobongela the express purpose of the liquid in 2 different bottles: "This one with a white lid boosts the immune system. This one with a blue lid fights the virus or whatever disease you have.." Ubhejane's supposed antiviral effect is again alluded to when she says "You will carry on drinking from the blue bottle because we will be focusing on fighting the disease or the virus in your body."
29. The evidence shows that Ubhejane is sold as an unregistered antiviral medicine. This is prohibited by the Medicines Act.

### **BREACH OF LABELLING REQUIREMENTS**

30. Section 18 of the Medicines Act, titled 'Labels and advertisements' states "No person shall sell any medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars."

31. Page 6 of Government Notice No 2025 states “the package in which a drug is sold, shall bear a label on which is stated in clear and indelible letters....the name and business address of the applicant in whose name the drug is registered...the requirements , if any, for the method of storage... the batch number of the drug, the expiry date of the drug where applicable, where practicable, the dose of the drug.. the quantity of the drug in the package...” unless the drug is dispensed by a “chemist, druggist, medical practitioner or dentist.”
32. None of the bottles of Ubhejane shown in the video were labelled.
33. It appears unlikely to be the case that the bottles of Ubhejane are dispensed by a “chemist, druggist, medical practitioner or dentist.”
34. Consequently, Mr Gwala appears to be breaching the labelling requirements of the Medicines Act.

### **FALSE AND MISLEADING ADVERTISEMENTS**

35. Section 20 of the Medicines Act, titled “Publication or distribution of false advertisements concerning medicines” states:
- “No person shall-
- (a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine; or
- (b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine is other than that stated by the council in terms of sub-paragraph (ii) of paragraph (a) of section twenty-two or state or suggest that any

medicine should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of sub-paragraph (iii) or paragraph (a) of that section.”

36. Furthermore, Mr Gwala should be investigated for breaching Section 20 of the Medicines Act which prohibits misleading claims concerning any medicine. I attach a copy of an advertisement for Ubhejane that appeared in the Newspaper Ilanga on December 2007 as annexure NK4.
37. This advert claims that Ubhejane increases CD4 count and lowers viral load.
38. This claim is very likely false and misleading. It is unsubstantiated because Ubhejane has never been tested in a randomized control trial to determine if it increases CD4 count and reduces viral load.
39. On 8 April 2008, the Advertising Standards Authority, following a complaint by the TAC, ordered that this advertisement must be withdrawn. I attach NK5, a copy of the ruling.

#### **THE IMPORTANCE OF THE MEDICINE ACT**

40. One of the aims of the Medicines Act is “to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered” and “to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines”.
41. In *Administrator, Cape v Raats Rontgen and Vermeulen (Pty) Ltd – 1992 (1) SA 245 (A)*, Kriegler AJA pointed out in his judgment that the Medicines Act was:

“put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensible to most. The man in the street- and indeed many medical practitioners – could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines. Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasises, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labelled and may be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised.”

42. Many of us in TAC know friends, family members, colleagues and others who have died or become ill because they have been sold untested medicines as treatments or cures for AIDS that have also been marketed as alternatives to registered antiretroviral medicines.
43. The scale of the HIV epidemic is immense. A large number of people with HIV are vulnerable to false, misleading and unsubstantiated claims about medicines that purportedly treat or cure the disease. Breaking the Medicines Act in the way done by Zeblon Gwala endangers lives. I therefore urge the Law Enforcement Unit of the Department of Health to be directed to investigate the activities of Zeblon Gwala and take appropriate action to stop his illegal actions.

**NOKHWEZI GETRUDE HOBOYI**

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SIGNED AND AFFIRMED BEFORE ME IN THE PRESCRIBED MANNER AT CAPE TOWN ON THIS \_\_\_\_\_ DAY OF APRIL 2008, THE DEPONENT HAVING STATED THAT SHE HAS NO OBJECTION TO AFFIRMING THE AFFIDAVIT AND THAT SHE REGARDS THE AFFIRMATION AS BINDING ON HER CONSCIENCE.

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**COMMISSIONER OF OATHS**