



30 May 2012

Ms Mandisa Hela
Registrar: Medicines Control Council
Per email: HelaM@health.gov.za

Advertising Standards Authority of South Africa
Per email: complaint@asasa.org.za

Health Professions Council of South Africa
Conduct and Ethics
Per email: simphiwes@hpcsa.co.za

The Southern African HIV Clinicians Society (the Society) wishes to express its grave concern regarding a product which is currently being advertised extensively on at least one regional radio station, as well as in several smaller local online and printed publications. The reason for our concern is that the product has no proven use and potentially poses a public health risk as it is misleading and Dr Hugh Brathwaite's actions are in contravention of the law.

The product, "DR HUGH DERMO BLUE PRESEX PROTECTION GEL", is a patented copper and zinc based protective lubricant gel i.e. a "microbicide", which was developed and patented by Dr Hugh Brathwaite of East London.

The development of a vaginal gel to prevent sexually transmitted infections such as HIV – known as a "microbicide" – is a global effort involving thousands of scientists, clinicians and many communities. Despite early evidence to show that such a microbicide may be possible to develop, there is currently no such microbicide which has been licenced by any country in the world, as no such product has been fully developed to date.

The radio advertisement which has been heard on Algoa FM in the Eastern Cape advocates the use of this untested microbicide product as an alternative to condoms to avoid unwanted pregnancies and infections. According to the advertisement, the gel contains copper and zinc, which Dr Brathwaite claims kills viruses, bacteria and fungi on contact. He recommends use of the product "when safe sex is better sex." To access further information, one is advised to make further contact via SMS. However, when the Society did this in order to better understand the nature of this misleading advert, there was no acknowledgement of our SMS or any form of response to the SMS, and certainly no additional information.

Coverage of the product in the local tabloids includes an article in Dispatch on 13 July 2011, as well as Township Times Online featuring the product, with claims from Dr Brathwaite that the product was approved by the MCC in 2007 and that it can stop transmission of HIV. This is a lie. He stated that the product contains copper and zinc, which have been experimentally shown to kill HIV, herpes virus and the papilloma virus, which causes cervical cancer and genital warts. Dr Brathwaite said the product could be used with condoms, but that further research has shown that the product would replace the condom. These claims are negligent and unlawful.



According to a follow up article in the Dispatch on 31 July 2011 (which was also posted on the SAMA Med-e-news, 01 August 2011), the MCC had no record of the registration of the product, and SANAC (South African National AIDS Council) questioned Dr Brathwaite's claims that it could prevent transmission of HIV. In this follow up article, Dr Brathwaite admitted that he could not make these claims, and that the product was not an orthodox medicine.

There is also a full page advertisement for the product which was placed in a publication called "East London Fever" on 11 November 2011, which makes similar misleading and unsupported claims about the product.

Gender Pharma (Pty) Ltd, a company that was established in July 2011, appears to be the distributor of the product on behalf of Dr Brathwaite. The company website contains scant information and some feeble disclaimers about the product. There is also an email address to request additional information regarding the product. Again, when the Society requested information (specifically any clinical trial data to support the efficacy of the product), there was no acknowledgement of the request, nor was any further information forthcoming.

One of the Society's roles is to advocate for the best possible HIV treatment, care and prevention for communities, and to ensure that any such interventions are based on sound evidence. Consequently, such reckless exploitation of a potentially vulnerable population is of the utmost concern to us. The Eastern Cape has a high burden of HIV disease, and some clinic attendees feel that there is a stigma attached to collecting condoms from the clinic. Thus, such an alternative – if effective – would be attractive.

Furthermore, women are still largely disempowered in parts of this region with regard to reproductive rights, and upon exposure to these advertisements may feel that they now have a safe alternative to condoms.

These misleading claims suggest that there is an easy alternative to the ABC (Abstain, Be faithful, Condomise) to prevent transmission of HIV and other sexually transmitted infections, and as such threatens to undo years of education to prevent infection. The advertisements also suggest that there is a contraceptive benefit to the product, which may encourage consumers to stop using their usual method of contraception, resulting in unplanned pregnancies. The impact of HIV and other sexually transmitted infections, as well as unplanned pregnancies, on the individual, the community and society is enormous. In the absence of any evidence to support the above claims, this is both scandalous and illegal.

According to the radio commercial, the product is available from "leading pharmacies" and costs about R12.00 for 2 sachets. For many South Africans, this is not an insubstantial cost, and they may be prompted to buy this product as a result of the misleading advertisements, wasting their limited resources on a product which can neither prevent infection nor pregnancy – and indeed, may cause harm. Pharmacies, like medical practitioners, have a duty to protect patients and advise products responsibly about matters pertaining to the community's health, including prevention of infection and family planning by proven methods. Promoting and selling this product would seem to contravene this duty.

As a Society, we feel that the advertising and distribution of an unlicensed product is irresponsible, unlawful and exploits the public by misleading them with fictitious claims. The



fact that Dr Hugh Brathwaite claims that it stops the transmission of HIV is a possible replacement for the condom is also of grave concern.

The Southern African HIV Clinicians Society demands the following:

- The immediate withdrawal of the product from any entity distributing the product;
- An immediate termination of any advertising campaigns relating to this product;
- An immediate investigation by the Health Professionals Council of SA into Dr Brathwaite's conduct, and appropriate sanction taken for any professional misconduct
- An immediate investigation by the Medicines Control Council into the illegal claims made by Dr. Brathwaite (and any other legal entity involved in the manufacture, distribution, marketing and/or sales of the product), and appropriate sanction; and
- That criminal charges be brought against Dr. Brathwaite for his illegal actions.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'Francesca Conradie'.

Dr Francesca Conradie
President: Southern African HIV Clinicians
Society

A handwritten signature in black ink, appearing to read 'Michelle Moorhouse'.

Dr Michelle Moorhouse
Board Member: Southern African HIV
Clinicians Society

cc:

Hon. Dr Pakishe Aaron Motsoaledi
The Minister: National Department of Health
Per email: masukm@health.gov.za; hadebf@health.gov.za

Professor PFK Eagles
Chairperson: Medicines Control Council
Per e-mail: peagles@uwc.ac.za.

Dr Fareed Abdullah
CEO: SANAC
Per email: fabdullah@sanac.org.za

Mrs Vuyiseka Dubula
TAC General Secretary
Per email: vuyiseka@tac.org.za / tantaswa@tac.org.za

Mr Mark Heywood
Executive Director: Section 27
Per email: heywood@section27.org.za

Algoa FM
Per fax: 08 22 30 7 000