

Caroline Taylor
Medicines Division
Medical and Healthcare Regulatory Authority.

Email: caroline.taylor@mhra.gsi.gov.uk

Dear Ms. Taylor,

On behalf of the Global Campaign for Microbicides and the International Rectal Microbicide Working Group we are writing to express our concern about the disease prevention claims being made by Kirklees Medical Ltd. in connection with the lubricants it manufactures.

The Global Campaign for Microbicides (GCM) is an international coalition of NGOs working to build support among policymakers, opinion leaders, and the general public for increased investment into microbicides and other user-controlled HIV prevention methods. Please see www.global-campaign.org for more information about GCM.

The International Rectal Microbicide Working Group is a network of nearly 500 scientists, policy makers and advocates from 38 countries on 5 continents dedicated to advancing the research and development of safe and effective rectal microbicides for the men and women who need them. Please visit www.IRMWG.org for more information.

Naturally, we have been very interested in Kirklees since it came to our attention last December that the company was making explicit claims regarding the ability of its products to reduce the risk of sexually transmitted HIV infection. In a December 18, 2006 e-mail to IRMWG from Christiaan Hohenzollern of Kirklees Medical, Mr. Hohenzollem stated that a Kirklees lubricant “is less than 50% effective against HIV in actual use between partners although it performed exceptionally well against other STIs”.

GCM has maintained an Unproven Product Claims Watch for several years now specifically to raise public awareness of products that are being presented to the public (without substantiating evidence) as effective microbicides and to advocate for the removal of such products from the market wherever possible. Knowing this, IRMWG referred this information about Kirklees to GCM and we have been working together on it for the last ten months; urging Kirklees to either provide us with peer-reviewed scientific data supporting its anti-HIV/anti-STI claims or to cease making them. The Terrence Higgins Trust, as a UK-based member of both the GCM and IRMWG, has taken the lead on generating this dialog, as you know.

We are disappointed and concerned that Kirklees has not complied with either of these two requests. Although they have provided some information about where and how their products have been tested, they have not provided data demonstrating either (1) anti-HIV efficacy in vivo or (2) that long-term use of the product is safe over time (i.e. does not damage either vaginal or rectal epithelia in any way that might increase HIV risk). The latter is also a critical factor since some candidate microbicides, the most notable being Nonoxynol-9, have been discarded from consideration because regular use of them caused epithelial damage that could actually facilitate the user's HIV risk.

Over two dozen candidate products are currently being tested by credible research institutions to determine their potential safety and efficacy for use as vaginal and/or rectal microbicides to

help prevent HIV transmission. No Kirklees product is currently among these candidates, however.

Robin Shattock, a leading microbicide researcher, directs pioneering laboratory work at St. George's Medical School in London. Among other things, St. George's screens compounds to determine if they are appropriate for investigation as potential microbicides. Dr. Shattock's lab has, in fact, already screened chlorohexidine gluconate (identified by Kirklees as an active ingredient in K-Lube) and ruled it out as a potential microbicide.

Despite this, Kirklees is nevertheless promoting its "microbicidal lubricant" on its website (see http://www.kirkleesmedical.com/acatalog/Latest_News.html) -- describing it as "personal lubricant that has anti-viral and antibacterial properties". They no longer appear to be making a direct anti-HIV claim on their own website (likely because of the nature of THT's conversation with them over the last several months). They are, however, stating that this "lubricant may reduce the risk of exposure to fluid-borne pathogens should the integrity of the latex barrier be compromised by overt failure or by permeation of viruses. Destruction of lymphocytes and macrophages may facilitate inactivation of HIV associated with these cells".

We would be glad to discuss with you why this language is inappropriate and what standard assays and clinical trials are used in the microbicides field to assess a candidate product's real effectiveness. We can also recommend well respected, London-based microbicide researchers to discuss these issues with you in person, if that would be useful.

In addition to its own website, Kirklees products continue to be actively promoted on websites that cater to people interested in anal sex, with language that implies very clearly that they provide some level of protection against HIV. At <http://www.fukk.it/acatalog/Lubes.html>, for example, you will see that K-Lube is described as "designed and [is] manufactured in the UK by Kirklees Medical, the ONLY lube manufacturer that puts fully medically tested and proven microbicides and parabens into its lubes to act as warrior and defender for your improved sexual safety - so you can play with added safety!"

At <http://pumphouse.me.uk/acatalog/Lubes.html>, you will see that both K-Lube original and K-Lube Menthol are described as having "anti-bacterial and anti-viral ingredients added to ensure your safe and continued enjoyment". This language also appears on a website called monsternuts.com (see http://www.monsternuts.net/cgi-bin/sh000001.pl?REFPAGE=http%3a%2f%2fwww%2emonsternuts%2enet%2facatalog%2fOnline_Catalogue%2ehtml&WD=lube&SHOP=%20&PN=Lubes%2ehtml%23a100#a100).

Finally, we should mention that, last March, some Belgian colleagues advised us that K-Lube was being sold as a 'microbicide' in at least one sex shop in Antwerp, with labelling explicitly stating that it was effective against HIV. Although we have not investigated this in depth, it seems very likely that K-Lube bottles with that labelling are still on the shelves in many sex shops in Europe, despite the recently revised language regarding HIV prevention capabilities on the Kirklees website.

As you know, unprotected anal intercourse is the sexual behavior capable of most efficiently transmitting HIV from one person to another. The decision to use unfounded public marketing claims leading consumers to believe that use of a product will reduce HIV risk during anal sex is, therefore, a real threat to public health.

Kirklees has defended these claims by saying that they always promote use of their product in conjunction with a condom. This is disingenuous, however, because there is no clinical evidence that the product does, in fact, provide any added protection if the condom slips or breaks. Even more problematic is the message to the consumer who has already made the decision not to use condoms – which is that the products will ensure his/her “safe and continued enjoyment”.

We appreciate the fact that you are looking into this matter and urge you to use the regulatory power of your office to compel Kirklees to stop making these claims unless they can provide compelling evidence to support them. Please feel free to let us know if we can be of assistance in any way with regard to this matter.

Thank you for your attention, vigilance and public health support.

Sincerely,



Anna Forbes
Deputy Director
Global Campaign for Microbicides
asforbes@path.org



Jim Pickett
Chair
International Rectal Microbicide Working Group
jpickett@aidschicago.org