



IRMWG Consensus Statement on Rectal Safety of Vaginal Microbicides – May 17, 2007

The International Rectal Microbicides Working Group (IRMWG) calls upon the microbicide community to support rectal safety trials of vaginal microbicides which have progressed to Phase III efficacy trials, and to ensure that the introduction of safe and efficacious vaginal microbicides shall not be delayed by collecting and reviewing rectal safety data.

Specifically the IRMWG urges:

- 1) Trial sponsors to fund rectal safety trials alongside all candidate vaginal microbicides in efficacy trials;
- 2) Donors to provide more resources for the field to conduct rectal safety trials; and,
- 3) Regulatory agencies to provide guidance describing reasonable rectal safety data needed to approve vaginal microbicides.

Purpose: The IRMWG strongly supports the collection of rectal safety data for all candidate vaginal microbicides in efficacy trials **to ensure information is provided to eventual users through appropriate product labelling and community education efforts.**

What if data shows signs of rectal toxicity in a candidate vaginal microbicide?

If available data show signs of rectal toxicity, the IRMWG **does not recommend halting or delaying the introduction of a vaginal microbicide.** The IRMWG recommends that eventual users be informed that the vaginal microbicide is not meant to be used rectally and that available data show signs of rectal toxicity. Product labelling and community education efforts should emphasize that using such a product may cause harm to the rectal mucosa and may increase the risks of HIV transmission if used while engaging in unprotected anal intercourse.

What if there are no data available on rectal safety of a candidate vaginal microbicide?

If no data are available, **the IRMWG does not recommend halting or delaying the introduction of the vaginal microbicide.** The IRMWG recommends that eventual users be informed that the vaginal microbicide in question is not meant to be used rectally, has not been proven to be effective when used rectally, and that there are no data on rectal safety for the specific product.

As a field, we should work diligently to avoid such a situation, since gathering rectal safety data should pose no delays to efficacy trials. Short safety trials can be conducted in parallel to efficacy trials.

Endorsed by:
African Microbicides Advocacy Group
Alliance for Microbicide Development
Global Campaign for Microbicides

For more information – www.IRMWG.org