Kilimanjaro Christian Medical Centre
KCMC-Duke University Kilimanjaro AIDS Program
DIADS Clinical Research Site
Pharmacy Procedures

Procedure for Importing Study Products into Tanzania

1. The local Investigator of Record submits the protocol to the Ethical Committee at KCMC.
2. The Ethical Committee grants approval of the protocol.
3. The protocol is submitted to the National Institute of Medical Research in Tanzania.
4. The National Institute of Medical Research grants approval.
5. The Pharmacist of Record requests a waiver from the Tanzania Food and Drugs Authority (TFDA) for any study products not included in the Tanzania Formulary. This may be required for most study products that are manufactured in the USA, since the manufacturer must register the product with TFDA for it to be included in the Tanzania Formulary. Most medications on the Tanzania Formulary are generic products that are manufactured in Asia, especially India. Some branded antiretrovirals are, however, on the Tanzania Formulary as second line agents.
6. TFDA grants the necessary waivers.
7. The study products may now be imported into Tanzania.
8. The above process may take as long as six months to complete if waivers are required from TFDA.
9. The Site Pharmacist at KCMC orders the study products from the supplier.
10. The supplier sends the Pharmacist of Record at KCMC a copy of the packing slip showing the expected date of arrival in Tanzania.
11. The KCMC pharmacist contacts the regional pharmacist at TDFA who must accompany the KCMC pharmacist to the airport and inspect the study products before they can be picked up.
12. After the first shipment is received, this procedure repeats for each subsequent shipment beginning with step 9.