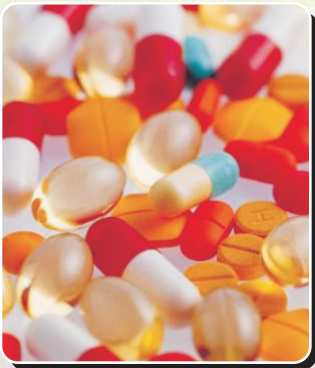


## The Pharmacy and Poisons Board...



The Pharmacy and Poisons Board (PPB) is the Drug Regulatory Authority of the Ministry of Medical Services. Established in 1957 under the Pharmacy and Poisons Act (Cap 244) Laws of Kenya, its mandate is to make better provision for the practice and profession of pharmacy and the trade in pharmaceutical products.

The work of the PPB is guided by its mission of improving the quality of life of Kenyans by ensuring the quality, safety and efficacy of pharmaceutical products and services.

The aim of most clinical trials is to test in humans, the safety and efficacy of new drugs and medical devices under development. Such interventions naturally fall under the ambit of the Pharmacy and Poisons Board as the national drug regulatory authority. As such, it is mandatory for any trial that includes the testing of drugs and medical devices in humans to obtain the necessary regulatory clearances and approvals from the Pharmacy and Poisons Board.

## The Expert Committee on Clinical Trials...

To address this function, the PPB has set up an Expert Committee on Clinical Trials (ECCT) with the remit of establishing a regulatory framework for the review and conduct of clinical trials in Kenya. A major function of the ECCT is to review all clinical trial protocols on investigational products (pharmaceuticals) and medical devices to be conducted in Kenya and to provide recommendations to the Board.

The ECCT has developed checklists and guidelines for submission of protocols. All protocols submitted to the ECCT will require prior approval by Institutional Review Boards (IRBs) and Ethics Committees (ECs) recognized by the National Council of Science and Technology (NCST).

The Department of Pharmacovigilance serves as the Secretariat of the ECCT.



## Correspondence...

All correspondence to the ECCT should be addressed as follows:

The Registrar,  
Pharmacy and Poisons Board,  
P.O. Box: 27663-00506,  
Nairobi, Kenya

Attention: The Expert Committee on Clinical Trials, Department of Pharmacovigilance

Tel: +254-(0)20-3562107, 2716905/6  
Mobile: +254-(0)72060881/(0)733884411  
Fax: +254-(0)202713431/2713409  
E-mail: [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org)  
[www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org)



Checklist for submitting documents to the ECCT can be downloaded from [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org) on clicking link on pharmacovigilance, or may be obtained from the PPB Headquarters



2010...

## Current Membership of the ECCT:

### Registrar:

Dr. K. C. Koskei, B.Pharm

### Deputy Registrar:

Dr. F. M. Siyoi, B.Pharm, MBA (Strategy)

### Chairman:

Prof. Gilbert Kokwaro, B.Pharm., MSc., PhD.  
University of Nairobi & Kenya Medical Research Institute

### Vice-Chairman:

Prof. Walter Jaoko, MBChB, MTMed, PhD  
University of Nairobi

### Members:

Dr. Rashid Aman, BPharm., PhD  
African Centre for Clinical Trials

Dr. Osanjo George, B.Pharm., Msc., PhD  
University of Nairobi.

Dr. Bernhards Ogutu, MBChB, MMed, PhD  
Kenya Medical Research Institute

Dr. Monique Wasunna, MBChB, MSc., PhD, DTM&H, DLSHTM  
Kenya Medical Research Institute

### PPB Secretariat:

Mr. G. Muthuri, HND.Pharm, BA.(Psy & Soc)

Dr. Edward Abwao, B. Pharm, MSc-MedStat

Dr. J. Pandit, M. Pharm-Clinical Pharmacy

## Flow of protocols to ECCT...



Review and Approval



## MINISTRY OF MEDICAL SERVICES PHARMACY AND POISONS BOARD

## The Expert Committee on Clinical Trials (ECCT)



2010

### Our mission:

To promote the rational search for new, better, more effective and safe drugs and medical devices.