GAZETTE NOTICe No. 1881

THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

(L.N. 192 of 2010)

It is notified that Form 1: Application for Registration of a Medical Device has been revised in accordance with the provisions of the Pharmacy and Poisons Act (Cap 244), The Pharmacy and Poisons (Registration of Drugs) Rules, Legal Notice Number 192 of 2010.

The template application form below prescribes the minimum information required for submission of dossiers for registration of a medical device seeking marketing authorization in Kenya. The applications should be submitted to the following address:

The Registrar,

Pharmacy and Poisons Board

Lenana Road,

P. O. Box 27663-00506,

NAIROBI, KENYA

For purposes of submission to PPB, an application for registration of medical device shall include:

(a) One duly filled application submitted as an electronic copy including their supporting documents - see Annex I: Application Form for Registration of Medical Device below

(b) Samples of the medical device.

(c) Payment of requisite application fees described in the guideline document for medical device issued by the Pharmacy and Poisons Board.

(d) Any other information required and described in the guideline document for medical device issued by the Pharmacy and Poisons Board.

ANNEX I: APPLICATION FORM FOR REGISTRATION OF MEDICAL DEVICE

(to be submitted as an electronic copy)

SECTION 1: DETAILS OF THE APPLICANT (as described in the guideline document for registration of a medical device issued by the Pharmacy and Poisons Board from time to time)

SECTION 2: PARTICULARS OF THE MANUFACTURER(S) OF THE MEDICAL DEVICE AND ACTIVITY DONE AT THE MANUFACTURING SITE(S) (as described in the guideline document for registration of a medical device issued by the Pharmacy and Poisons Board from time to time)

SECTION 3: TECHNICAL PARTICULARS OF THE MEDICAL DEVICE (as described in the guideline document for registration of a medical device issued by the Pharmacy and Poisons Board from time to time)

SECTION 4: SAFETY AND POST MARKET SURVEILLANCE PLAN OF THE FINISHED PRODUCT (as described in the guideline document for registration of a medical device issued by the Pharmacy and Poisons Board from time to time)

SECTION 5: ANY OTHER REFERENCE TO SUPPORT THE APPLICATION (as described in the guideline document for registration of a medical device issued by the Pharmacy and Poisons Board from time to time)

SECTION 6: DECLARATION BY AN APPLICANT which must be signed, dated and authenticated by an Official stamp. No received without properly authenticated declaration.

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application file is available for verification during GMP inspection.

I also agree that I am obliged to follow the requirements of the Pharmacy and Poisons Board which are related to medical devices.

I also agree that the undersigned has not marketed or advertised this medical device in Kenya and will follow the PPB requirements for advertisements of products.

I also agree that the undersigned will implement a Post-Market Surveillance plans for this medical device in accordance with PPB requirements.

I also consent to the evaluation of information provided to the Pharmacy and Poisons Board.