ANNEX I

SCHEDULE (r.4)

Form 1

APPLICATION FORM FOR REGISTRATION OF HERBAL AND COMPLEMENTARY MEDICINE

(to be submitted in one hard copy and one electronic copy on a CD-ROM)

CONFIDENTIAL

The Registrar,
Pharmacy and Poisons Board,
P. O. Box 27663-00506,
Lenana road,
NAIROBI.

Application Number		
Date of submission of the dossier		
1ST Evaluator	Name	Signature
2ND Evaluator	Name	Signature
Date of 1st evaluation		
Date of 2nd Evaluation		
Number of volumes of files received		
1. PARTICULARS OF THE APPLICANT		
1.1 Name of the Applicant, Physical Address, Telephone, Fax and Email		
1.2 Name of the Local Technical Representative (for imported products only), Physical Address, Telephone, Fax and Email		
2. PARTICULARS OF THE PRODUCT		
2.1 Product Name of the product		
2.2 Dosage form and strength of the product		
2.3 Therapeutic use(s) of the product		
2.4 Visual description of the product		
2.5 Type of container of the product		
2.6 Pack size(s) of the product		
2.7 Proposed Shelf life (in months) of the product		
2.8 Storage conditions of the product		
2.9 Country of origin of the product		
2.10 Status of registration of the product in the country of origin, authorization/registration number *(attach Certificate of Pharmaceutical product)*		

3. PARTICULARS OF THE MANUFACTURER

3.1 Name of the Manufacturer, Physical Address of the manufacturing site, Telephone, Fax and Email	
3.2 GMP status of the manufacturing site	

4. COMPOSITION OF THE PRODUCT

4.1 List all active ingredient(s) used

Scientific or Botanical Name	Common Name or Synonym	Part of Plant used	Specification (USP, BP, or In house)	Quantity per dosage unit	Chemical Constituent(s)

4.2 List all non active ingredient(s) used

Scientific or Botanical Name	Common Name or Synonym	Part of Plant used (where applicable)	Specification	Quantity per dosage unit	Reason for inclusion

5. QUALITY CONTROL OF RAW MATERIALS

5.1 Botanical identification of the Plant used	
5.1.1 **Botanical name**	
5.1.2 Brief description of the living plant	
5.1.3 Macroscopic identification	
5.1.4 Microscopic identification	
5.2 Geographical source of the plant used	
5.3 Harvesting of the plant	
5.3.1 Stage of plant during harvesting	
5.3.2 Time of harvesting	
5.3.3 Season of harvesting	
5.4 Method of drying	
5.5 Storage of plant materials	
5.6 Evaluation of plant materials	

5.6.1 Purity Tests to include likely adulterants e.g. soil, pesticides, radioactive contamination, microbiological limits, animal droppings, other plant parts, heavy metals etc	
5.6.2 Qualitative and quantitative tests of the plant materials	
6. QUALITY CONTROL OF THE FINISHED PRODUCT	
6.1 Specification of the Finished Product	
6.2 Brief Description of the manufacturing procedure and in process quality controls (attach batch manufacturing records)	
6.3 Analysis of the Finished Product	
6.4 Certificate Of Analysis from an Independent Recognized Quality Control Laboratory	
6.5 Packaging and Labeling of the Finished Product (include Package Insert)	
7. STABILITY STUDIES OF THE FINISHED PRODUCT	
8. PHARMACOLOGICAL AND TOXICOLOGICAL INFORMATION	
8.1 Safety of the Product	
8.1.1 Ethno-medical information (Literature search)	
8.1.2 Toxicity Studies	
8.2 Pharmacological Information of the Product	
8.2.1 Efficacy studies of the product	
8.2.2 Dosage regimen	
8.2.3 Adverse/Side Effects	
8.2.4 Contraindications, Warning and precautions	

Declaration by an applicant

1. 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.
2. I further confirm that the information referred to in my application file is available for verification during GMP inspection.
3. I also agree that I am obliged to follow the requirements of the Pharmacy and Poisons Board which are related to herbal and complementary medicines.
4. I also agree that the undersigned has not marketed or advertised this product in Kenya and will follow the PPB requirements for advertisements of medicines
5. I also agree that the undersigned will implement a Pharmacovigilance plans for this product in accordance with PPB requirements
6. I also consent to the evaluation of information provided to the Pharmacy and Poisons Board.

Name: ……

Position in the company: ……

Signature and Date: ……

Official stamp: ……

OVERALL COMMENTS AND QUERIES	
Conclusion of the assessment RECOMMENDED (no outstanding issues) QUERY RAISED REJECTED (Please delete which does not apply)	