(Made under Regulation 5(1) (b) and 16(1))

ANNEX I: APPLICATION FORM FOR MARKETING AUTHORIZATION OF VETERINARY MEDICINAL PRODUCTS

General Instructions:

Provide as much detailed, accurate and final information as possible. Note that all areas are to be filled out by the applicant EXCEPT were indicated by grey areas which are for TMDA Official Use Only!

Should you have any questions regarding this form, please contact the Tanzania Medicines and Medical Devices Authority (TMDA).

A properly filled out and signed original copy of the form (including a copy in MS Word should be uploaded in TMDA portal). The entire Common Technical Document should also be submitted with the application and forwarded to TMDA through portal after all particulars are filled in accordingly and the application is saved to generate tracking number (TRC number)

Application Number	
Number of files	
Anatomic Therapeutic Classification (ATC) Code	
Invented Product Name (if relevant)	
International Non-proprietary Name (INN) of the Active substance (active substance), strength, pharmaceutical form.	
Product strength	
Name and complete address of the Applicant (Market Authorization Holder)	
Name(s) and complete address (es) of the manufacturer(s) of the finished product(s), including the final product release if different from the manufacturer. (Add as many rows as necessary)	
Name and address (es) of the manufacturer(s) of the Active substance(s). (Add as many rows as necessary)	
Name and complete address of the Local Agent	
Packaging and pack size	
Number of samples	
Proposed shelf life (months)	
Proposed forensic category	
Registration status in other countries (e.g. SADC and EAC)	

Composition				
Ingredients	Unit (mg)	Specifications	Quantity per batch (kg)	Functions
Core tablet/Contents of capsule				

Subtotal 1				
Film coating/Hard capsule				
Subtotal 2				
Grand total				

Name and signature of the applicant:

Date:

Official stamp