

	APPLICATION FORM FOR MARKETING AUTHORIZATION OF VETERINARY MEDICINAL PRODUCTS	<i>TMDA/DMC/MRE/F/006</i> <i>Rev #: 01</i>
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(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 where 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 on a CD-ROM) must be submitted together with other application documents. The entire Common Technical Document should be submitted both as hard-copy and on CD-ROM. The application should be sent to the following address:

Director General
Tanzania Medicines and Medical Devices
P.O. Box 77150
EPI Mabibo
Off Mandela Road
Dar-es-Salaam
Tanzania

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				



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Subtotal 1				
Film coating/Hard capsule				
Subtotal 2				
Grand total				

Name and signature of the applicant:

Date:

Official stamp