S/No.	Document name	Document number
Medicines Registration Regulations		
1.	The Tanzania Medicines and Medical Devices (Scheduling of Medicines) Regulations, 2015	Government Notice No. 63
2.	The Tanzania Medicines and Medical Devices (Controls of Drugs and Herbal Drugs Promotions) Regulations, 2010	Government Notice No. 160
3.	The Tanzania Medicines and Medical Devices (Registration of Medicinal Products) Regulations, 2015	Government Notice No. 314
4.	The Tobacco Products (Regulations) (Designation of Inspectors) Notice, 2021	Government Notice No. 360
5.	The Tanzania Medicines and Medical Devices (Orphan Medicines) Regulations, 2018	Government Notice No. 412
6.	The Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021	Government Notice No. 686
Guidelines		
7.	Compendium of Guidelines for Marketing Authorization of Human Medicinal Products, 1st revision, July, 2020	TMDA/DMC/MRE/G/001
8.	Guidelines on Variations on Registered Medicinal Products, March 2020	TMDA/DMC/MRE/G/002
9.	Guidelines on Submission of Documentation for Renewal of Marketing Authorization of Human and Veterinary Medicinal Products, January 2021	TMDA/DMC/MRE/G/003
10.	Guidelines on Submission of Documentation for Registration of Veterinary Medicinal Products, March	TMDA/DMC/MRE/G/004

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	2020	
11.	Guidelines for Control of Promotion and Advertisement of Medicines, Medical Devices and Cosmetics in Tanzania, 1st Edition, January 2015	TFDA/DMC/MI&E/G/005
12.	Guidelines on Submission of Documentation for Registration of Immunological Veterinary Products, March, 2020	TMDA/DMC/MRE/G/005
13.	Guidelines on Submission of Documentation for Marketing Authorization of Human Vaccines, March 2020	TMDA/DMC/MRE/G/006
14.	Guidance on Processing of Applications for Registration of Medicinal Products through Non-Routine Procedure in Tanzania, August 2021	TMDA/DMC/MRE/G/007
15.	Guidelines on Submission of Documentation for Marketing Authorization of Similar Biotherapeutic Products, March 2020.	TMDA/DMC/MRE/G/008
16.	Guidelines on Submission of Documentation for Marketing Authorization of Biotherapeutic Products, March 2020	TMDA/DMC/MRE/G/009
17.	Guidance For Assessors of Quality, Safety and Efficacy of Human Medicinal Products, September 2022	TMDA/DMC/MRE/G/010
18.	Guidance for Production of Alcohol-Based Hand Sanitizers Under Public Health Emergency Preparedness, April 2020	TMDA/DMC/MRE/G/011
19.	Guidelines for Submission of Documentation for Marketing Authorization of Biocidal (Antiseptics and Disinfectants) Products, August 2020	TMDA/DMC/MRE/G/012

20.	Guidelines on Submission of Documentation for Marketing Authorization of Herbal Medicinal Products, July 2020	TMDA/DMC/MRE/G/013
21.	Guidelines on Variation of Registered Vaccines February, 2021	TMDA/DMC/MRE/G/014
22.	Guidance for Assessors of Quality, Safety and Efficacy of Vaccines, 2022	TMDA/DMC/MRE/G/015
23.	Guidelines on Good Review Practices, September, 2022	TMDA/DMC/MRE/G/016
24.	Guidelines for Emergency Use Authorization of Medicinal Products, September 2022	TMDA/DMC/MRE/G/018
25.	Good Regulatory Practices for Medical Products, March 2023	TMDA/DMC/MRE/G/019
26.	Good Reliance Practices, March 2023	TMDA/DMC/MRE/G/020
SOPs (Standard Operating Procedures)		
27.	Procedure for Receiving and distributing Applications for Registration of Medicines	TMDA/DMC/MRE/SOP/001
28.	Procedure for Evaluation of Medicinal Product Dossier	TMDA/DMC/MRE/SOP/002
29.	Procedure for Withdrawal of Registration of Medicinal Products	TMDA/DMC/MRE/SOP/003
30.	Procedure for Technical Committee Meetings and Publishing Information of Registered Medicinal Products	TMDA/DMC/MRE/SOP/004
31.	Procedures for Handling of Medicines Registration Samples	TMDA/DMC/MRE/SOP/005
32.	Procedure for Competency Assessment and Categorization of Medicines Assessors	TMDA/DMC/MRE/SOP/006
33.	Procedure for Receiving Application for Approval of	TMDA/DMC/MRE/SOP/007

	Medicinal Products Promotional Materials	
34.	Procedure for Evaluation of Medicines Promotional Material	TMDA/DMC/MRE/SOP/008
35.	Procedure for Preparation of List of Registered Medicines and Refused Applications for Gazetting	TMDA/DMC/MRE/SOP/009
36.	Procedure for Handling of Fast Track Medicinal Product Applications	TMDA/DMC/MRE/SOP/010
37.	Procedure For Handling of Applications for Emergency Use Authorization	TMDA/DMC/MRE/SOP/011
38.	Procedure for approval and Rejection of Applications and Communication with Applicants	TMDA/DMC/MRE/SOP/012
39.	Procedure for engagement of external experts in regulatory activities	TMDA/DMC/MRE/SOP/013
40.	Procedure for developing and publishing of TMDA Public Assessment Reports (TPARS) and Summary of Product Characteristics (SmPC's)	TMDA/DMC/MRE/SOP/014
41.	Procedure for Evaluation of Antiseptics and Disinfectants	TMDA/DMC/MRE/SOP/015
42.	Procedure for Receiving and Distributing Application for Registration of Medicines Under EAC Joint Assessment Procedure	TMDA/DMC/MRE/SOP/016
43.	Procedure for Evaluation of Medicinal Product Dossier under EAC Joint assessment Procedure	TMDA/DMC/MRE/SOP/017
44.	Procedure for Handling Medicines Evaluation Reports and Letters for EAC Joint Assessment Applications	TMDA/DMC/MRE/SOP/018
45.	Procedures for Handling Applications of WHO Prequalified Medicinal Products & SRA Approved Products Submitted Under Collaborative Registration	TMDA/DMC/MRE/SOP/019

	Procedure (CRP)	
46.	Procedures for Handling of Application for Registration of Orphan Medicinal Products	TMDA/DMC/MRE/SOP/020
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47.	Process flow chart for registration of Medicinal Product	TMDA/DMC/MRE/PF/001
48.	Process flow chart for approval of Promotional Material of Medicinal Product	TMDA/DMC/MRE/PF/002
49.	Process flow chart for Registration of Antiseptics and Disinfectants	TMDA/DMC/MRE/PF/003
50.	Process flow chart for approval of Notification of Tobacco	TMDA/DMC/MRE/PF/004
51.	Process flow chart for re- registration of Medicinal Product	TMDA/DMC/MRE/PF/005
52.	Process flow chart for Variations Process Flow Chart	TMDA/DMC/MRE/PF/006
53.	Process flow chart for Registration of Orphan Medicinal Products	TMDA/DMC/MRE/PF/007
Forms		
54.	Almanac of Human Medicines Technical Committee Meetings	TMDA/DMC/MRE/F/001
55.	Almanac of Veterinary Medicines Technical Committee Meetings	TMDA/DMC/MRE/F/002
56.	Evaluation Report template for Medicines Promotional materials	TMDA/DMC/MRE/F/003
57.	Application for Change of Local Agents (Local Technical Representatives)	TMDA/DMC/MRE/F/004

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58.	Application for Variation of a Registered Human Medicinal Product in Tanzania	TMDA/DMC/MRE/F/005
59.	Application for Marketing Authorization of Veterinary Medicinal Products	TMDA/DMC/ MRE /F/006
60.	Application form for registration of Medicinal Product	TMDA/DMC/MRE/F/007
61.	Notice of suspension/cancellation of Marketing Authorization of a Medicinal Products	TMDA/DMC/MRE/F/008
62.	Evaluation report template of Variation of Registered Medicinal Product	TMDA/DMC/MRE/F/010
63.	Evaluation report template of Renewal of Registered Medicinal Product	TMDA/DMC/MRE/F/011
64.	Template for evaluation report of Query Response	TMDA/DMC/MRE/F/012
65.	Template for Patient Information Leaflet	TMDA/DMC/MRE/F/015
66.	Template for writing of TMDA Public Assessment Reports (TPARS)	TMDA/DMC/MRE/F/016
67.	External Expert Performance Evaluation Form	TMDA/DMC/MRE/F/017
68.	Code of Conduct for TMDA External Experts	TMDA/DMC/MRE/F/018
69.	Terms of reference for Human Medicines Registration Technical Committee	TMDA/DMC/MRE/F/019
70.	Terms of reference for Veterinary Medicines Registration Technical Committee	TMDA/DMC/MRE/F/020
71.	Application Form for New Registration of Antiseptic and Disinfectants	TMDA/DMC/MRE/F/021
72.	Application Form for Renewal of Registration of Antiseptic and Disinfectants	TMDA/DMC/MRE/F/022
73.	Application Form for Variation of a Registered Antiseptic or Disinfectants	TMDA/DMC/MRE/F/023

74.	Application Form for Approval of Promotional Materials	TMDA/DMC/MRE/F/024
75.	Application Form for Trade Fair Permit	TMDA/DMC/MRE/F/025
76.	Application Form for Marketing Authorization of Herbal Medicinal Product	TMDA/DMC/MRE/F/026
77.	Vaccine Variation Application Form	TMDA/DMC/MRE/F/027
78.	Evaluation Template for Antiseptics/Disinfectants	TMDA/DMC/MRE/F/028
79.	Medicines Assessors Categorization Form	TMDA/DMC/MRE/F/029
80.	Products Recommended for Registration	TMDA/DMC/MRE/F/030
81.	Applicant's consent to share Assessment and Inspection reports with NMRA's	TMDA/DMC/MRE/F/031
82.	Evaluation report template of New Applications	TMDA/DMC/MRE/F/032
83.	List of Withdrawn Products Form	TMDA/DMC/MRE/F/033
84.	Application For Marketing Authorization for Human Vaccines	TMDA/DMC/MRE/F/034
85.	Medicines Registration Evaluation - Organogram	TMDA/DMC/MRE/F/035
86.	List of Documents Governing Medicines Review Process	TMDA/DMC/MRE/F/036
87.	Timelines for processing of applications and Marketing Authorization of Medicinal Product	TMDA/DMC/MRE/F/037
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88.	Checklist for Technical Screening of Online Applications for Registration of a Medicinal Product	TMDA/DMC/MRE/C/001
89.	Screening Checklist for Applicants submitting New Applications for Marketing Authorization	TMDA/DMC/MRE/C/002
90.	Assessment Report Appraisal Checklist	TMDA/DMC/MRE/C/003
91.	Checklist for screening of applications for approval	TMDA/DMC/MRE/C/004

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92.	Checklist for preparation of Human Medicines Registration Technical Committee Meeting	TMDA/DMC/MRE/C/005
Registers		
93.	New applications of medicinal samples movement register	TMDA/DMC/MRE/R/001
94.	Renewal application of medicinal samples movement register	TMDA/DMC/MRE/R/002
95.	Application for variation of a medicinal samples movement register	TMDA/DMC/MRE/R/003
96.	Register of External medicines assessor	TMDA/DMC/MRE/R/004
97.	Expired medicines samples movement register	TMDA/DMC/MRE/R/005
98.	Received Sample of Medicinal Products Register	TMDA/DMC/MRE/R/006
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99.	Certificate of Medicinal Product registration	TMDA/DMC/MER/CF/001