

S/No.	Document name	Document number
Medici	ines 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
Guideli	nes	
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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1.	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







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20.	Guidelines on Submission of Documentation for Marketing Authorization of Herbal Medicinal Products, July 2020	
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. OPs	Good Reliance Practices, March 2023 (Standard Operating Procedures)	TMDA/DMC/MRE/G/020
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/002
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30.	Publishing Information of Registered Medicinal Products Procedures for Handling of Medicines Registration Samples	she rates of Sh.

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57.	Application for Change of Local Agents (Local Technical Representatives)	TMDA/DMC/MRE/F/004







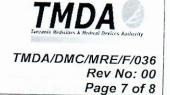


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69.	Terms of reference for Human Medicines Registration	TMDA/DMC/MRE/F/019
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71.	Application Form for New Registration of Antiseptic	TMDA/DMC/MRE/F/021
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85.	Medicines Registration Evaluation - Organogram	TMDA/DMC/MRE/F/035
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93.	New applications of medicinal samples movement register	TMDA/DMC/MRE/R/001
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