

GOVERNMENT NOTICE No. 27

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT, 2019
(No. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) (AMENDMENT) REGULATIONS, 2026

IN EXERCISE of the powers conferred by section 129 of the Pharmacy and Medicines Regulatory Authority Act, 2019, I, MADALITSO BALOYI, Minister of Health and Sanitation, make the following Regulations—

1. These Regulations may be cited as the Pharmacy and Medicines Regulatory Authority (Fees and Forms) (Amendment) Regulations, 2026, and shall come into force on 1st April, 2026.

Citation
2. The Pharmacy and Medicines Regulatory Authority (Fees and Forms) Regulations, 2022 are amended, by deleting the *First Schedule* and substituting therefor, a new *First Schedule* as follows—

Amendment of G.N. 9 of 2022

“FIRST SCHEDULE reg. 2
FEES

Matter	Fees
1 Registration fees for pharmacy personnel: inclusive of both application and issuance of a certificate—	
(a) pharmacist—	
(i) indexing	K 50,000.00
(ii) Malawian pharmacist, including internship . .	K 75, 000.00
(iii) non-Malawian pharmacist, including internship . .	USD 500.00
(iv) Malawian pharmacist	K 100, 000.00
(v) non-Malawian pharmacist including vetting . .	USD1, 000.00
(vi) Malawian pharmacist re-examination, per subject	K 50,000.00
(vii) non-Malawian pharmacist re-examination per subject	USD 215.00
(viii) examination remark, per subject	K 100,000.00
(ix) non-Malawian volunteer pharmacist	USD 500.00
(b) pharmacy technologist or technician—	
(i) indexing	K 50,000.00
(ii) Malawian pharmacy technologist or technician including internship	K 50,000.00
(iii) non-Malawian pharmacy technologist or technician including internship	USD 250.00
(iv) Malawian pharmacy technologist or technician . .	K 60,000.00

<i>Matter</i>				<i>Fees</i>	
(v)	non-Malawian pharmacy technologist or technician, including vetting	..	..	USD	700.00
(vi)	Malawian pharmacy technologist or technician re-examination, per subject	..	..	K	40,000.00
(vii)	non-Malawian pharmacy technologist or technician re-examination, per subject	..	..	USD	200.00
(viii)	examination remark, per subject	..	..	K	100,000.00
(ix)	non-Malawian volunteer pharmacy technologist or technician	..	..	USD	300.00
(c)	pharmacy assistant—				
(i)	indexing	..	..	K	50,000.00
(ii)	Malawian pharmacy assistant including internship			K	50,000.00
(iii)	non-Malawian pharmacy assistant including internship			USD	250.00
(iv)	Malawian assistant	..	..	K	40,000.00
(v)	non-Malawian pharmacy assistant, including vetting			USD	500.00
(vi)	Malawian pharmacy assistant re-examination per subject	..	..	K	30,000.00
(vii)	non-Malawian pharmacy assistant re-examination per subject	..	..	USD	200.00
(viii)	examination remark per subject.	..	..	K	100,000.00
(ix)	non-Malawian volunteer pharmacy assistant			USD	300.00
(d)	medical representative—				
(i)	Malawian medical representative	..	..	K	500,000.00
(ii)	non-Malawian medical representative.	..	..	USD	1,500.00
2	Retention fees for pharmacy personnel—				
(a)	pharmacist—				
(i)	Malawian pharmacist	..	..	K	60,000.00
(ii)	non-Malawian pharmacist	..	..	USD	600.00
(iii)	non-Malawian volunteer pharmacist	..	..	USD	350.00
(b)	pharmacy technologist or technician—				
(i)	Malawian pharmacy technologist or technician	..	..	K	40,000.00
(ii)	non-Malawian pharmacy technologist or technician			USD	350.00
(iii)	non-Malawian volunteer pharmacy technologist or technician	..	..	USD	300.00
(c)	pharmacy assistant—				
(i)	Malawian pharmacy assistant	..	..	K	30,000.00
(ii)	non-Malawian pharmacy assistant	..	..	USD	200.00
(iii)	non-Malawian volunteer pharmacy assistant			USD	200.00

<i>Matter</i>		<i>Fees</i>	
(d)	medical representative—		
(i)	Malawian medical representative	K	300,000.00
(ii)	non-Malawian medical representative	USD	750.00
3	Licensing of premises—		
(a)	Malawian manufacturer, manufacturing licence—		
(i)	inspection and processing for oral dosage forms, general (solids and liquids)	K3,500,000.00	
(ii)	inspection and processing for oral dosage forms, beta and cephalosporins (solids and liquids)	K3,500,000.00	
(iii)	inspection and processing for external preparation	K2,500,000.00	
(iv)	inspection and processing for sterile preparations general (solids and liquids)	K4,000,000.00	
(v)	inspection and processing for sterile preparations (beta and cephalosporins)	K4,000,000.00	
(vi)	inspection and processing for hormones, general oral solids dosage form	K3,500,000.00	
(vii)	inspection and processing for hormones, sterile	K4,000,000.00	
(viii)	inspection and processing for primary and secondary packaging	K3,500,000.00	
(ix)	inspection and processing for medical oxygen gas	K3,000,000.00	
(x)	re-inspection of manufacturing premises, if previously failed, follow-up or investigation	*Cost of travel	
(b)	non-Malawian manufacturer, manufacturing licence—		
(i)	within the Southern Africa Development Community	USD 4,000.00	
(ii)	from the rest of Africa	USD 5,500.00	
(iii)	from outside Africa	USD 6,500.00	
(iv)	additional category for good manufacturing practice	USD 2,000.00	
(v)	desk review, per manufacturing plant	USD 3,500.00	
(vi)	desk review, additional category for good manufacturing practice	USD 1,000.00	
(c)	wholesale pharmacy licence—		
(i)	inspection and processing	K2,000,000.00	
(ii)	re-inspection fees of premises, if previously failed, reopening after closure or investigations	*cost of travel	
(d)	retail pharmacy licence—		
(i)	inspection and processing	K1,500,000.00	
(ii)	re-inspection fees of premises, if previously failed, reopening after closure or investigations	*cost of travel	
(e)	medicine store licence or veterinary shop licence—		
(i)	inspection and processing	K 500,000.00	

<i>Matter</i>		<i>Fees</i>
	(ii) re-inspection fees of premises, if previously failed, reopening after closure or investigations ..	*cost of travel
(f)	dispensing licence—	
	(i) inspection and processing for a private facility with admission service	K1,200,000.00
	(ii) inspection and processing for a private facility without admission service	K 350,000.00
	(iii) inspection and processing for a public facility and a facility operated by Christian Health Association of Malawi facility with admission service ..	K 500,000.00
	(iv) inspection and processing for an institutional facility	K1,000,000.00
	(v) inspection and processing for a health centre ..	K 385,000.00
	(vi) re-inspection fees of premises, if previously failed, re-opening after closure or investigations ..	*cost of travel
(g)	medical device licence—	
	(i) inspection and processing	K1,500,000.00
	(ii) re-inspection fees of premises, if previously failed, re-opening after closure or investigations ..	*cost of travel
4	Retention fees for premises—	
(a)	manufacturing licence—	
	(i) premises with oral dosage forms (solids and liquids)	K 500,000.00
	(ii) premises with external preparations	K 300,000.00
	(iii) premises with sterile preparations	K 500,000.00
	(iv) primary packaging only	K 300,000.00
	(v) secondary packaging only	K 200,000.00
(b)	wholesale pharmacy licence—	
	(i) retention fees	K1,000,000.00
	(ii) inspection for relocation or alterations to premises	K1,000,000.00
(c)	retail pharmacy licence—	
	(i) retention fees	K 500,000.00
	(ii) inspection for relocation or alterations to premises	K 750,000.00
(d)	medicine store and veterinary shop licence—	
	(i) retention fees	K 200,000.00
	(ii) inspection for relocation or alterations to premises	K 300,000.00
(e)	dispensing licence—	
	(i) retention for a facility with admission services ..	K 600,000.00
	(ii) relocation or alterations to premises processing for a facility with admission services	K 400,000.00
	(iii) retention for a facility without admission services	K 200,000.00

<i>Matter</i>		<i>Fees</i>
(iv)	relocation or alterations to premises processing for a facility without admission services	K 200,000.00
(v)	retention of an institutional facility	K 600,000.00
(vi)	inspection for relocation or alteration to premises for an institutional facility	K 300,000.00
(f)	medical device licence—	
(i)	retention fees.	K 750,000.00
(ii)	inspection for relocation or alterations to premises	K 800,000.00
5	Registration of medicinal products—	
(a)	human medicines—	
(i)	generic medicine manufactured in Malawi ..	K 800,000.00
(ii)	line extension of generic medicine manufactured in Malawi	K 500,000.00
(iii)	generic medicine manufactured outside Malawi ..	USD 1,700.00
(iv)	line extension of generic medicine manufactured outside Malawi	USD 1,000.00
(v)	new chemical entity including dosage form or delivery system manufactured outside Malawi. . . .	USD 2,200.00
(vi)	biologicals manufactured outside Malawi ..	USD2,000.00
(vii)	renewal or re-registration of medicine manufactured in Malawi	K 500,000.00
(viii)	renewal or re-registration of medicine manufactured outside Malawi	USD 1,000.00
(ix)	*orphan medicine manufactured outside Malawi	USD 500.00
(x)	administration fee for issuance of Certificate of Pharmaceutical Product	K 100,000.00
(b)	veterinary medicines—	
(i)	generic medicine manufactured in Malawi ..	K 600,000.00
(ii)	line extension of generic medicine manufactured in Malawi	K 400,000.00
(iii)	generic medicine manufactured outside Malawi	USD 1,200.00
(iv)	line extension of generic medicine manufactured outside Malawi	USD 750.00
(v)	new chemical entity including dosage form or delivery system manufactured outside Malawi. . . .	USD 1,700.00
(vi)	biologicals manufactured outside Malawi ..	USD 1,500.00
(vii)	renewal or re-registration of medicine manufactured in Malawi	K 400,000.00
(viii)	renewal or re-registration of medicine manufactured outside Malawi	USD 750.00

<i>Matter</i>		<i>Fees</i>	
6	Retention fees for medicinal products—		
(a)	human medicines—		
(i)	medicines manufactured in Malawi	K 500,000.00	
(ii)	medicines manufactured outside Malawi ..	USD 700.00	
(iii)	orphan medicine	USD 300.00	
(b)	veterinary medicines—		
(i)	medicines manufactured in Malawi	K 300,000.00	
(ii)	medicines manufactured outside Malawi ..	USD 600.00	
7	*Registration of allied substances—		
(a)	medical devices—		
(i)	class I manufactured in Malawi	K 150,000.00	
(ii)	class I manufactured outside Malawi ..	USD 700.00	
(iii)	class II manufactured in Malawi	K 500,000.00	
(iv)	class II manufactured outside Malawi ..	USD 1,000.00	
(v)	class III manufactured in Malawi	K1,000,000.00	
(vi)	class III manufactured outside Malawi ..	USD 1,700.00	
(vii)	renewal or re-registration of class I manufactured in Malawi	K 100,000.00	
(viii)	renewal or re-registration of class I manufactured outside Malawi	USD 500.00	
(ix)	renewal or re-registration of class II manufactured in Malawi	K 300,000.00	
(x)	renewal or re-registration of class II manufactured outside Malawi	USD 700.00	
(xi)	renewal or re-registration of class III manufactured in Malawi	K 800,000.00	
(xii)	renewal or re-registration of class III manufactured outside Malawi	USD 1,000.00	
(b)	cosmetics—		
(i)	manufactured in Malawi	K 300,000.00	
(ii)	manufactured outside Malawi	USD 700.00	
(iii)	renewal or re-registration of cosmetics manufactured in Malawi	K 150,000.00	
(iv)	renewal or re-registration of cosmetics manufactured outside Malawi	USD 500.00	
(c)	nutritional supplements—		
(i)	manufactured in Malawi	K 200,000.00	
(ii)	manufactured outside Malawi	USD 700.00	
(iii)	renewal or re-registration of nutritional supplements manufactured in Malawi ..	K 150,000.00	

<i>Matter</i>			<i>Fees</i>		
	(iv)	renewal or re-registration of nutritional supplements manufactured outside Malawi	..	USD	400.00
(d)	traditional medicines—				
	(i)	manufactured in Malawi	..	K	200,000.00
	(ii)	manufactured outside Malawi	..	USD	700.00
	(iii)	renewal or re-registration of traditional medicines manufactured in Malawi	..	K	150,000.00
	(iv)	renewal or re-registration of traditional medicines manufactured outside Malawi	..	USD	400.00
(e)	disinfectants and reagents—				
	(i)	disinfectants and reagents manufactured in Malawi		K	300,000.00
	(ii)	disinfectants and reagents manufactured outside Malawi	..	USD	500.00
	(iii)	renewal or re-registration of disinfectants and reagents manufactured in Malawi	..	K	200,000.00
	(iv)	renewal or re-registration of disinfectants and reagents manufactured outside Malawi	..	USD	300.00
(f)	feed additives—				
	(i)	feed additives and supplements manufactured in Malawi	..	K	300,000.00
	(ii)	feed additives and supplements manufactured outside Malawi	..	USD	500.00
	(iii)	renewal or re-registration of feed additives and supplement manufactured in Malawi	..	K	200,000.00
	(iv)	renewal or re-registration of feed additives and supplements manufactured outside Malawi	..	USD	300.00
(g)	*fast-track registration of medicines or allied substances manufactured outside Malawi				
			..	twice the normal rate	
8	*Retention of allied substances—				
(a)	medical devices—				
	(i)	class I manufactured in Malawi	..	K	100,000.00
	(ii)	class I manufactured outside Malawi	..	USD	300.00
	(iii)	class II manufactured in Malawi	..	K	200,000.00
	(iv)	class II manufactured outside Malawi	..	USD	400.00
	(v)	class III manufactured in Malawi	..	K	500,000.00
	(vi)	class III manufactured outside Malawi	..	USD	1,000.00
(b)	cosmetics—				
	(i)	cosmetics manufactured in Malawi	..	K	100,000.00
	(ii)	cosmetics manufactured outside Malawi	..	USD	500.00

<i>Matter</i>	<i>Fees</i>
(c) nutritional supplements—	
(i) nutritional supplements manufactured in Malawi . .	K 100,000.00
(ii) nutritional supplements manufactured outside Malawi	USD 500.00
(d) traditional medicines—	
(i) traditional medicines manufactured in Malawi . .	K 100,000.00
(ii) traditional medicines manufactured outside Malawi	USD 500.00
(e) disinfectants and reagents—	
(i) disinfectants and reagents manufactured in Malawi	K 100,000.00
(ii) disinfectants and reagents manufactured Outside Malawi	USD 200.00
(f) feed additives and supplements—	
(i) feed additives and supplements manufactured in Malawi	K 100,000.00
(ii) feed additives and supplements manufactured outside Malawi	USD 300.00
9 Review of post-registration changes—	
(a) notification for a product manufactured in Malawi . .	K 100,000.00
(b) notification for a product manufactured outside Malawi	USD 150.00
(c) minor variation for a product manufactured in Malawi . .	K 150,000.00
(d) minor variation for a product manufactured outside Malawi	USD 200.00
(e) major variation for a product manufactured in Malawi . .	K 250,000.00
(f) major variation for a product manufactured outside Malawi	USD 500.00
10 Assessment and issuing of permit for importation or exportation of medicines and allied substances—	
(a) import or export permit for registered medicines, per consignment, based on invoice total value including freight charge and insurance	1.5% of invoice value
(b) verification fees for commercial consignments and donations to commercial organizations based on invoice total value including freight charge and insurance	1% of invoice value
(c) importation of unregistered medicines or allied substances from authorized sources based on invoice total including freight charge and insurance	7% of invoice value
(d) verification and approval fees for a consignment of medicines or allied substances for disasters, outbreak, and raw materials	exempted
(e) amendment of import permit	K 200,000.00
(f) verification fees for donations to non-profit making charitable Non-Governmental Organisation	K 50,000.00
(g) narcotics permit	K 100,000.00

<i>Matter</i>				<i>Fees</i>
(h)	amendment of narcotics permit	..	..	K 50,000.00
(i)	import or export permit for investigational medicinal product	..	..	K 100,000.00
(j)	amendment of import or export permit for investigational medicinal product	..	..	K 50,000.00
11	Analysis of samples by the quality control laboratory—			
(a)	*routine drug analysis per batch	..	..	USD36.00 – USD1,200.00
(b)	male latex condoms per batch	..	..	USD 700.00
(c)	samples analysis at laboratories outside the Authority	..	..	cost of analysis plus 12% service charge
(d)	re-analysis of samples at owner's or importer's request	..	..	USD 880.00
(e)	detailed certificate of analysis at the owner of samples request	..	..	USD 385.00
(f)	analysis of sample under investigation	..	..	USD 200.00
12	Clinical trials—			
(a)	application			
(i)	phase I	..	..	USD 9,000.00
(ii)	phase II	..	..	USD 6,000.00
(iii)	phase III	..	..	USD 5,000.00
(iv)	clinical trial for *academic research	..	..	USD 2,000.00
(b)	amendment of clinical trial—			
(i)	major amendment	..	..	USD 300.00
(ii)	minor amendment	..	..	USD 100.00
(iii)	renewal of clinical trial	..	..	USD 2,200.00
(c)	fast-track application for clinical trial	..	..	twice the normal rate
13	Vetting of health product promotional materials, per language—			
(a)	written materials—			
(i)	originating within Malawi	..	..	K 80,000.00
(ii)	originating outside of Malawi	..	..	USD 150.00
(b)	audio, video and written script—			
(i)	originating within Malawi	..	..	K 150,000.00
(ii)	originating outside of Malawi	..	..	USD 150.00
(c)	posters or billboards on any medium including the internet—			
(i)	originating within Malawi	..	..	K 100,000.00
(ii)	originating outside of Malawi	..	..	USD 150.00
(d)	posters on vehicles—			
(i)	originating within Malawi	..	..	K 80,000

<i>Matter</i>				<i>Fees</i>	
	(ii)	originating outside of Malawi		USD	150.00
(e)	t-shirts—				
	(i)	originating within Malawi		K	50,000.00
	(ii)	originating outside of Malawi		USD	150.00
(f)	other materials such caps, wall clocks, watches, umbrellas, bags—				
	(i)	originating within Malawi		K	50,000.00
	(ii)	originating outside of Malawi		USD	150.00
14	Education—				
	(a)	processing and vetting for a pharmacy college	..	K	500,000.00
	(b)	inspection of pharmacy college		*cost of travel	
	(c)	curriculum review of diploma and certificate courses	..	K2,000,000.00	
	(d)	curriculum review of degree courses		K3,000,000.00	
	(e)	retention certificate for pharmacy assistant training school		K	300,000.00
	(f)	retention certificate for pharmacy technician training school		K	400,000.00
	(g)	retention certificate for pharmacist training school	..	K	500,000.00
	(h)	letter of good standing for Malawian		K	100,000.00
	(i)	letter of good standing for non-Malawian		USD	200.00
	(j)	application for exemption from continuous professional development exemption		K	50,000.00
15	Authority publications—				
	(a)	set of Statutes and Statutory Instruments		K	100,000.00
	(b)	Code of Ethics		K	20,000.00
	(c)	dangerous drugs register		K	50,000.00
	(d)	pharmacist register book		K	20,000.00
	(e)	continuous professional development policy and guideline		K	20,000.00
	(f)	continuous professional development logbook	..	K	20,000.00
	(g)	pharmacist standardised curriculum		K	350,000.00
	(h)	pharmacy technician standardized curriculum	..	K	300,000.00
	(i)	pharmacy assistants standardised curriculum..	..	K	250,000.00
16	Miscellaneous—				
	(a)	inspection on demand		*cost of travel	
	(b)	disposal application fee		K	50,000.00
	(c)	supervision of pharmaceutical products disposal	..	*cost of travel	
	(d)	medicine disposal certificate		K	60,000.00
	(e)	handling fee for seized products, per kilogram	..	K	3,000.00

<i>Matter</i>				<i>Fees</i>	
(f)	disposal of seized products	..	..	disposal fee x weight of products seized	
(g)	change of particulars on register	..	..	K 120,000.00	
(h)	notification and processing of change of pharmacy practice premises	..	..	..	K 100,000.00
(i)	licence re-print	..	..	..	K 120,000.00
(j)	medical camps	..	..	..	USD 200.00

Note:

1. *Cost of travel shall be based on total distance to be covered to and from the premises and allowance for the number of days to be spent by inspectors.
2. *Orphan medicine is a pharmaceutical agent developed specifically to treat certain rare medical condition that affects a small percentage of the population.
3. *Fast track implies the registration process leading to granting of the product license shall be expedited and prioritized depending on compelling circumstances.
4. *In regards to registration of allied substances, the fees for medical devices, traditional medicines, nutritional supplements, cosmetics, feed and feed additives, and disinfectants manufactured in Malawi apply solely to the processing of the application. The applicant shall additionally bear the costs associated with sampling of registration samples to be conducted by the Authority.
5. *In regards to retention of allied substances, all products not retained for the previous year(s) without presenting evidence of approved withdrawal notice by the Authority shall attract a regulatory penalty equivalent to full fee of one year of retention before re-instatement on the register upon payment of required retention fee for the year it is to be reinstated.
6. *The fees for routine drug analysis shall depend on the type of test and dosage form as shall be indicated on a tabulated chart published by the Authority from time to time.
7. *Academic research refers to a clinical trial submitted to the Authority by a student as part of the requirements for the award of an academic qualification.”.

Made this 27th day of March, 2026.

(FILE NO. PMRA/MOH/26/02/2026)

M. BALOYI
Minister of Health and Sanitation