Vol. 660 12 June Junie 2020 No. 43418

PART 1 OF 2

For purposes of reference, all Proclamations, Government Notices, General Notices and Board Notices published are included in the following table of contents which thus forms a weekly index. Let yourself be guided by the gazette numbers in the righthand column:

Weekly Index

Alle Proklamasies, Goewermentskennisgewings, Algemene Kennisgewings en Raadskennisgewings gepubliseer, word vir verwysingsdoeleindes in die volgende Inhoudopgawe ingesluit wat dus weeklikse indeks voorstel. Laat uself deur die Koerantnommers in die regterhandse kolom lei:

Weeklikse Indeks

Contents

DEPARTMENT OF CO-OPERATIVE GOVERNANCE

NO. 653 **12 JUNE 2020**

Dr Nkosazana Dlamini-Zuma Local Municipality

Main Street, P.O. Box 62, Creighton, 3263

PUBLIC NOTICE

2020/2021 FINAL INTEGRATED DEVELOPMENT PLAN (IDP), FINAL SPATIAL DEVELOPMENT FRAMEWORK (SDF) AND FINAL BUDGET

Notice is hereby given that the Council of Dr Nkosazana Dlamini-Zuma Municipality has sat on the 28th May 2020 to consider the following documents as tabled by the Mayor:

- The final IDP for 2020/2021 financial year in terms of Section 28(2) of the Municipal Systems (Act 32 of 2000), Section 16(2) of the Municipal Finance Management Act (56 of 2003).
- The final SDF for 2020/2021 financial year in terms of Section 28(2) of the Municipal Systems Act of 2000, and Section 16 (2) of Municipal Finance Management Act (56 of 2003).
- The final Budget for 2020/2021 financial year in terms of Chapter 4 of the Municipal Systems Act, No. 32 of 2000, read with Section 22 of the Municipal Finance Management Act, 56 of 2003 and in terms of Section 16(1) of the MFMA.

The 2020/2021 Final Budget is now available for viewing in the Municipal Buildings and on the Municipal website and the municipality will assist those who require assistance in the determination of rates payables.

DESCRIPTION	2020/2021 FINAL BUDGET	2021/2022 BUDGET YEAR	2022/2023 BUDGET YEAR
REVENUE			
Property Rates	-36 718 924	-38 407 995	-40 174 762
Service Charges	-3 608 330	-3 774 313	-3 947 932
Licences and Permits	-784 798	-820 899	-858 660
Fines	-624 362	-653 083	-683 125
Government Grants and Subsidies	-170 627 000	-177 498 494	-190 649 557
Interest Earned -External Investments	-8 089 720	-8 461 847	-8 851 092
Other Revenue	-10 512 020	-11 001 849	-11 507 934
Total Revenue	**-230 971 155**	**-240 618 480**	**-252 673 062**
EXPENDITURE			
Employee related costs	70 219 449	73 219 943	76 828 223
Councillors remuneration	11 901 110	12 448 561	13 021 195
Programmes	14 934 567	15 454 197	16 165 091
General expenditure	41 392 015	42 649 384	44 091 146
Repairs and maintenance	11 748 335	12 288 926	12 854 393
Other expenditure (Provisions)	53 080 560	53 576 956	56 111 450
Total Operating Expenditure	**203 276 037**	**209 872 696**	**219 071 499**

CAPITAL EXPENDITURE			
Municipal Infrastructure Grant	26 989 000	29 050 000	30 559 000
Municipal Disaster Grant	85 000	0	0
Other Expenditure	74 003 478	12 153 468	12 712 800
Total Capital Expenditure	**101 077 478**	**41 203 468**	**43 271 800**
TOTAL BUDGET (OPEX + CAPEX)	**304 353 515**	**251 076 437**	**262 343 299**
Integrated National Electrification	6 930 000	6 000 000	6 000 000

DR NDZ FINAL TARIFFS OF CHARGES FOR 2020/2021

Notice is hereby given in terms of the Local Government Municipal Systems Act No. 32 of 2000 and Municipal Property Rates Act No.6 of 2004, that the final Budget of the Dr Nkosazana Dlamini Zuma Municipality for 2020/2021 in terms of the Local Government Municipal Finance Management Act No. 56 of 2003.

Goods /Service	**Dr Nkosazana Dlamini Zuma Municipality Tariffs Include CPI(p/a) 2019/2020**	**Dr Nkosazana Dlamini Zuma Municipality Tariffs 2020/2021**
RAT01: RESIDENTIAL PROPERTIES	**1,61c/R**	**1,68c/R**
RAT02: BUSINESS, COMMERCIAL, INDUSTRIAL PROPERTIES	**2,47c/R**	**2,69c/R**
RAT03: AGRICULTURAL PROPERTIES	**0,40c/R**	**0,42c/R**
RAT04: PUBLIC SERVICE PURPOSES	**1,61c/R**	**1,68c/R**
RAT05: PSI	**0,40c/R**	**0,42c/R**
RAT06: PBO	**0,40c/R**	**0,42c/R**
RAT08: TOURISM & HOSPITALITY	**2,47c/R**	**2,69c/R**
RAT10: RESIDENTIAL SMALL HOLDING	**1,61c/R**	**1,68c/R**
RAT12: VACANT LAND	**1,61c/R**	**1,68c/R**
REFUSE REMOVAL		
Government Housing	672,00	702,00
Residential Properties	3991,00	4171,00
Residential Properties: Creighton, Bulwer and Donnybrook	1312,00	1371,00
Tourism & Hospitality Urban properties	3991,00	4171,00

Agriculture & Residential smallholding properties	3991,00	4171,00
Bulk Refuse	R94 200,00	98 439,00
Goods /Service		
Business and other properties are billed for the sum of the business within each Centre/Mall/Property.		
Business & Other properties		
Commercial	5224,00	5 459,00
Large	20380,00	21 297,00
"Significant volume of waste and difficult to handle"		
Medium	10083,00	10 537,00
Small	4935,00	5 157,00
Garden Refuse (per load)	262,00	274,00
Illegal Dumping		
All illegal dumping will be charge R3000 as a fine (NEW)		

VALUE ADDED TAX MUST BE ADDED TO ALL TARIFFS LISTED BELOW (EXCEPT TO FINES, REFUNDABLE DEPOSITS, INTEREST CHARGES OR WHERE INDICATED AS INCLUSIVE OF VALUE ADDED TAX)					2019/20 (INCL VAT)	2020/21 (INCL VAT)
			(bb)	Refundable deposit (refer to note below)	R842,00	**R879.00**
		(vi)	**Banners:**			
			(aa)	Per banner	R306,00	**R319,00**
			(bb)	Refundable deposit (refer to note below)	R210,00	**R219,00**
		(vii)	**Flags:**			
			(aa)	Per banner	R306,00	**R319,00**
			(bb)	Refundable deposit (refer to note below)	R210,00	**R219,00**
		(vii)	**Advertising vehicles**			
			(aa)	Per vehicle	R3118,00	**R3 258,00**
			(bb)	Refundable deposit (refer to note below)	R526,00	**R550,00**
		(viii)	**Private sale signs**			
			(aa)	Application fee	R755,00	**R789,00**
			(bb)	Refundable deposit (refer to note below)	R315,00	**R329,00**

		(ix)	**Construction signs**			
			(aa)	Application fee	R768,00	**R803,00**
			(bb)	Refundable deposit (refer to note below)	R315,00	**R329,00**
				NOTE: Deposits paid will be refunded provided that all posters and banners have been removed to the satisfaction of the Municipality's Building Inspectorate.		
		Permanent signs				
	(b)	**Aerial Advertisements**				
		(i)	Application fee - first 5sqm		R378,00	**R395,00**
		(ii)	Additional - per sqm		**R108,00**	**R113,00**
		(iii)	Monthly display fee per sign		**R78,00**	**R82,00**
		(iv)	Annual display fee per sign		R714,00	**R746,00**
	c)	**Advertising Vehicles**				
		(i)	Application fee		**R765,00**	**R799,00**
		(ii)	Monthly display fee per sign		**R1439,00**	**R1 504,00**
		(iii)	Annual display fee per sign		**R14 391,00**	**R15 039,00**
	(d)	**Building Attachment Signs**				

VALUE ADDED TAX MUST BE ADDED TO ALL TARIFFS LISTED BELOW (EXCEPT TO FINES, REFUNDABLE DEPOSITS, INTEREST CHARGES OR WHERE INDICATED AS INCLUSIVE OF VALUE ADDED TAX)				**2019/20 (INCL VAT)**	**2020/21 (INCL VAT)**
		(i)	Application fee - first 5sqm	R378,00	**R395,00**
		(ii)	Additional - per sqm	**R108,00**	**R112,00**
		(iii)	Monthly display fee per sign	**R78,00**	**R82,00**
		(iv)	Annual display fee per sign	R714,00	**R746,00**

Due dates for rates and refuse

1.1 That the final date for payment of annual rates be fixed at 28 September 2020 with a 3.2% discount for full payment upfront.

1.2 That rates and refuse are payable over a period of twelve equal instalments with the first instalments payable on or before the last day of August 2020. Thereafter each monthly instalment must be paid on or before the last working day of each month. Interest/penalties will accrue at 18% per annum if an instalment is not paid by the last working day of the month, and a flat 10% collection charge will be charged on any monthly instalments that fall two months into arrears, in terms of the Council's Credit Control and Debt Collection Policy

1.3 Business and Commercial has been increased by 9% in order for its tariffs to be in line with municipal rates ratio between the residential and non-residential categories of property of 1:2 which is for Business and Commercial Properties compared to residential property tariffs.

1.4 All other tariffs of charges for services rendered by the municipality will be increased by 4,5% unless other increase below 4,9% has been indicated in this document or budget document.

All Stakeholders, members of the public and the entire community of Dr Nkosazana Dlamini Zuma Local Municipality, Government Institutions, private sector and civil society organizations are hereby invited to view the documents and submit representations in connection with the aforesaid documents

Hard copies of the above documents are available for public viewing at the following places:

1. Dr Nkosazana Dlamini-Zuma Local Municipality, Main Street, Creighton
2. Dr Nkosazana Dlamini-Zuma Local Municipality, 32 Arbuckle Street, Himeville
3. Creighton Community Library, Bulwer Community Library, Underberg Library
4. The Municipal Website at www.ndz.gov.za

All comments should be made in writing and submitted for the attention of the Municipal Manager within 21 days from the date of public notice 2020.

Any technical enquiries regarding the aforementioned document may be addressed to: Office of The Municipal Manager to the attention of the Chief Financial Officer Mr K.B.M Mzimela and Mrs N.N Vakalisa.

Lesi yisaziso isigungu esilawula uMkhandlu iDr Nkosazana Dlamini Zuma sahlala mhla zingama 25 kuNdasa 2020 ukubheka, sicubungule siphinde siphasise lemibiko elandelayo eyethulwa umeya woMkhandlu:

- Uhlaka losomqulu wentuthuko edidiyelwe (IDP) ka 20202021 ngokwesahluko 28(2) ye Municipal Systems Act 32 ka 2000, nesahluko 16(2) ose Municipal Finance Management Act 56 of 2003.

- Uhlaka lwe SDF for 2020/2021 ngokwesahluko 28(2) ye Municipal Systems Act 32 of 2000, nesahluko 16(2) ose Municipal Finance Management Act 56 of 2003.

- Uhlaka lohlahlo-mali ka 2020/2021 Financial year ngokwesahluko 4 we Municipal systems Act No 32 of 2000, Kanye nesahluko 22 se Municipal Finance Management Act No.56 of 2003 nesahluko 16(1) se MFMA.

Bonke abathintekayo sibala amalunga omphakathi, osomabhizinisi, iminyango kaHulumeni, izinhlangano zomphakathi bavumelekile ukuthi bathumele izethulo zabo ngalemibiko.

Yonke imibono mayibhalwe ithunyelwe kuMphathi woMkhandlu ngaphambi kwezinsuku ezingamashumi amabili nanye emuva kwalesaziso. Ngencazelo eyengeziwe ungaxhumana no Mrs NN Vakalisa ehhovisi loMphathi kaMasipala ku 039 833 1038

Mr N.C. Vezi
Municipal Manager

DEPARTMENT OF ENVIRONMENT, FORESTRY AND FISHERIES

NO. 654 12 JUNE 2020

NATIONAL ENVIRONMENTAL MANAGEMENT: AIR QUALITY ACT, 2004 (ACT NO. 39 OF 2004)

DRAFT SECOND GENERATION AIR QUALITY MANAGEMENT PLAN FOR VAAL TRIANGLE AIRSHED PRIORITY AREA

I, Barbara Dallas Creecy, Minister of Forestry, Fisheries and the Environment, hereby, under section 19 read with section 57(1) of the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004), give notice of my intention to publish the second generation Air Quality Management Plan (AQMP) for Vaal Triangle Airshed Priority Area (VTAPA). The draft second generation AQMP for Vaal Triangle Airshed Priority Area can be downloaded on the following website: .

Members of the public are invited to submit to the Minister, within 60 days from the date of the publication of this notice in the *Gazette*, written inputs or comments on the draft second generation Air Quality Management Plan (AQMP) for Vaal Triangle Airshed Priority Area (VTAPA) to the following addresses:

By post to: The Director-General: Department of Environment, Forestry and Fisheries
Attention: Mrs Ricca Marowe
Private Bag X447
Pretoria
0001

By hand at: 473 Steve Biko Road, Environment House, Arcadia, Pretoria

By e-mail:

Any inquiries in connection with the notice can be directed to Dr Vincent Gololo at 012 399 9203 or by Email: ; or Mrs Ricca Marowe at 012 399 9207.

Comments received after the closing date may not be considered.

BARBARA DALLAS CREECY

MINISTER OF FORESTRY, FISHERIES AND THE ENVIRONMENT

PUBLIC NOTICE

NATIONAL ENVIRONMENTAL MANAGEMENT: AIR QUALITY ACT, 2004 (ACT NO. 39 OF 2004)

PROPOSED SECOND GENERATION AIR QUALITY MANAGEMENT PLAN FOR VAAL TRIANGLE AIRSHED PRIORITY AREA

The Minister of Forestry, Fisheries and the Environment, under section 19 read with section 57(1) of the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004), publish the proposed Second Generation Air Quality Management Plan (AQMP) for Vaal Triangle Airshed Priority Area (VTAPA), for public consultation. The draft second Generation AQMP for Vaal Triangle Airshed Priority Area can be downloaded on the following website:

Members of the public are invited to submit to the Minister, within 60 days from the date of the publication of this notice in the *Gazette*, written inputs or comments on the draft second generation Air Quality Management Plan (AQMP) for Vaal Triangle Airshed Priority Area (VTAPA) to the following addresses:

By post to: The Director-General: Department of Environment, Forestry and Fisheries
Attention: Mrs Ricca Marowe
Private Bag X447
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By hand at: 473 Steve Biko Road, Environment House, Arcadia, Pretoria

By e-mail:

Any inquiries in connection with the notice can be directed to Dr Vincent Gololo at 012 399 9203 or by Email: ; or Mrs Ricca Marowe at 012 399 9207.

Comments received after the closing date may be disregarded.

DEPARTMENT OF ENVIRONMENT, FORESTRY AND FISHERIES

NO. 655 12 JUNE 2020

NATIONAL ENVIRONMENTAL MANAGEMENT: AIR QUALITY ACT, 2004 (ACT NO. 39 OF 2004)

DRAFT SECOND GENERATION AIR QUALITY MANAGEMENT PLAN FOR VAAL TRIANGLE AIRSHED PRIORITY AREA

I, Barbara Dallas Creecy, Minister of Forestry, Fisheries and the Environment, hereby, under section 19 read with section 57(1) of the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004), give notice of my intention to publish the second generation Air Quality Management Plan (AQMP) for Vaal Triangle Airshed Priority Area (VTAPA). The draft second generation AQMP for Vaal Triangle Airshed Priority Area can be downloaded on the following website: www.saaqis.org.za

Members of the public are invited to submit to the Minister, within 60 days from the date of the publication of this notice in the *Gazette*, written inputs or comments on the draft second generation Air Quality Management Plan (AQMP) for Vaal Triangle Airshed Priority Area (VTAPA) to the following addresses:

By post to: The Director-General: Department of Environment, Forestry and Fisheries
Attention: Mrs Ricca Marowe
Private Bag X447
Pretoria
0001

By hand at: 473 Steve Biko Road, Environment House, Arcadia, Pretoria

By e-mail: [redacted]

Any inquiries in connection with the notice can be directed to Dr Vincent Gololo at 012 399 9203 or by Email: [redacted]; or Mrs Ricca Marowe at 012 399 9207

Comments received after the closing date may not be considered.

BARBARA DALLAS CREECY

MINISTER OF FORESTRY, FISHERIES AND THE ENVIRONMENT

DEPARTMENT OF HEALTH

NO. 656 **12 JUNE 2020**

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO THE REGISTRATION OF PERSONS AND THE MAINTENANCE OF REGISTERS: AMENDMENT REGULATIONS, 2019

The Minister of Health intends, in consultation with the South African Pharmacy Council, in terms of section 14 of the Pharmacy Act, 1974 (Act No. 53 of 1974), to make the Regulations in the Schedule.

The proposed amendments to these Regulations enable:

a) the establishment of a new category of pharmacy support personnel – pharmacy technician – with a new scope of practice;
b) the categorisation of pharmacy technicians as a type of pharmacist's assistant to enable these persons to handle medicines in accordance with the provisions of the Medicines and Related Substances Act, 1965, (Act 101 of 1965);
c) the retention of the categories of pharmacy support personnel - pharmacist's assistants (basic) and pharmacist's assistants (post-basic) - with amendments to the scope of practice;
d) two routes for the education and training and subsequent registration of pharmacy technicians – one via the Occupational Qualifications Sub-framework (OQSF), and the other via the Higher Education Qualifications Sub-framework (HEQSF);
e) registration of persons undertaking a pharmacy technician qualification which falls under the HEQSF, as a pharmacy technician (student) and completion of a traineeship whilst registered as a pharmacy technician (trainee);
f) registration of persons undertaking a pharmacy technician qualification which falls under the OQSF as a pharmacy technician (learner) and the option to exit as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) after completion of part

qualifications. NOTE: There is no traineeship or internship required after completing these part-qualifications or the whole qualification;

g) upskilling of current pharmacist's assistants, whilst enabling those who are unable to undergo further education and training to continue to practise in the category in which they are registered.

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

Any person wishing to comment on or make representation with regard to the proposed amendments to the Regulations is hereby invited to do so within three (3) months of the date of publication of this notice.

All such comments and representations must be submitted in writing using the format outlined in the attached template (available on www.health.gov.za), marked for the attention of Ms Mihloti Mushwana, Director: Public Entities Governance in any one of the following ways:

(a) Hand delivered to:
Director-General: Health
National Department of Health
222 Thabo Sehume Street
Pretoria
0001

(b) By electronic mail: regulationcomments@health.gov.za

Comments received after the closing date may not be considered. Enquiries may be made to Mandie Bhembe on (012) 395 8288/8130 or regulationcomments@health.gov.za.

DR. ZWELINI LAWRENCE MKHIZE, MP
MINISTER OF HEALTH
DATE 24/03/2020

GENERAL EXPLANATORY NOTE:

_____ Words underlined with a solid line indicate insertions in existing enactments.

SCHEDULE

Definitions

1. In this Schedule the "the Regulations" means the Regulations Relating to the Registration of Persons and the Maintenance of Registers published under Government Notice No. 1160 of 20 November 2000.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended by—

(a) the deletion of the definition of "certificate of qualification" after the definition of "certificate of approval"

(b) the substitution for the definition of **" continuing professional development "** of the following definition:

"continuing professional development" means the process by which persons registered under this Act maintain and enhance their competence throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training;";

(c) the substitution for the definition of **"pharmacist's assistant"** of the following definition:

"**"pharmacist's assistant"** means a natural person registered in one of the following categories:

(a) pharmacist's assistant (learner basic);

(b) pharmacist's assistant (basic);

(c) pharmacist's assistant (learner post-basic);

(d) pharmacist's assistant (post-basic);

(e) pharmacy technician (learner);

(f) pharmacy technician (student);

(f) pharmacy technician (trainee);

(g) pharmacy technician; or

(h) pharmacy student;

which constitute the various categories of pharmacy support personnel registered as such in terms of the Act';

(d) the insertion after the definition of **"pharmacist's assistant"** of the following definitions:

" **'pharmacy technician'** means a person registered as such in terms of the Act;

'pharmacy technician (learner)' means a person registered as such in terms of the Act;

'pharmacy technician (student)' means a person registered as such in terms of the Act;

'pharmacy technician (trainee)' means a person registered as such in terms of the Act;";

(e) the substitution for the definition of **"provider"** of the following definition:

" **'provider'** means any person or institution approved by and registered with the council in terms of the Act to provide education and training approved by the council for purposes of:

(a) registration as a pharmacist;

(b) registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician;

(c) registration of a speciality;

(d) continuing professional development;

(e) supplementary training; or

a course determined by the Council in terms of the Medicines Act;";

(f) the deletion of the definition of **"qualification in pharmacy"** after the definition of provider;

(g) the deletion of the definition of **"retail pharmacy"**

(h) the insertion after the definition of **"supplementary training"** of the following definition:

""**traineeship"** means practical training, as determined by council from time to time, undertaken by a pharmacy technician (trainee) in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by council for purposes of such training;";

(i) the substitution for the definition of **"tutor"** of the following definition:

""**tutor"** means a pharmacist registered with the council as a tutor, to supervise the internship of a pharmacist intern, the traineeship of a pharmacy technician (trainee) or the in-service training of a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic);"; and

(j) the insertion after the definition of **"wholesale pharmacy"** of the following definition:

" **'work-based training'** means education and training undertaken by a pharmacist's assistant (learner basic); pharmacist's assistant (learner post-basic), or pharmacy technician (learner) in a pharmacy under the auspices of a provider, as part of an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic); pharmacist's assistant (post-basic), or pharmacy technician. ".

Substitution of regulation 2 of the Regulations

3. The following regulation is hereby substituted for regulation 2 of the Regulations:

"**Categories of persons that may be registered**

2. For purposes of registration in terms of the Act, there shall be the following categories of persons:

(a) Pharmacy student;

(b) Pharmacist intern;

(c) Pharmacist;

(d) Specialist pharmacist;

(e) Pharmacist's assistant (learner basic);

(f) Pharmacist's assistant (basic);

(g) Pharmacist's assistant (learner post-basic);

(h) Pharmacist's assistant (post-basic);

(i) Pharmacy technician (student);

(j) Pharmacy technician (learner);

(k) Pharmacy technician (trainee);

(l) Pharmacy technician;

(m) Pharmacy owner;

(n) Responsible pharmacist;

(o) Nominee;

(p) Tutor;

(q) Provider;

(r) Assessor; and

(s) Moderator,

who must be registered by council in registers kept for these categories.".

Substitution of regulation 3 of the Regulations

4. The following regulation is hereby substituted for regulation 3 of the Regulations:

"**Requirements and conditions for registration as pharmacy student**

3. Any person registered with a provider to undertake an education and training programme approved by the council for purposes of registration as a pharmacist, must register with the council as a pharmacy student at the commencement of the first year of study: Provided that no person shall be registered as a pharmacy student with the council unless he or she complies with the provisions of regulation 4.".

Amendment of regulation 4 of the Regulations

5. Regulation 4(1) of the Regulations is hereby amended by—

(a) the substitution for paragraph *(b)* of the following paragraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable study permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and";

(b) the substitution for paragraph *(c)* of the following paragraph:

"*(c)* acceptable documentary evidence from the provider concerned that he or she has been admitted to the first or subsequent year of study for an education and training programme approved by the council for purposes of registration as a pharmacist; and".

Amendment of regulation 6 of the Regulations

6. Regulation 6(1) of the Regulations is hereby amended by the substitution for paragraph *(a)* of the following paragraph:

"(a) who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist"

Amendment of regulation 7 of the Regulations

7. Regulation 7 of the Regulations is hereby amended by the substitution for paragraph *(b)* of sub-regulation (1) of the following paragraph:

"*(b)* acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted for the first or subsequent year of an education and training programme approved by the council for purposes of registration as a pharmacist; and".

Amendment of regulation 8 of the Regulations

8. The following regulation is hereby substituted for regulation 8 of the Regulations:

8. Requirements and conditions for registration as a pharmacist intern.—Any person who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist must register as a pharmacist intern with the council: provided that no person shall be registered as a pharmacist intern, unless he or she complies with regulation 9.

Amendment of regulation 9 of the Regulations

9. Regulation 9(1) of the Regulations is hereby amended by—

(a) the substitution for paragraph *(b)* of the following paragraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and";

(b) the substitution for paragraph (d)(iii) of the following paragraph:

"(d)(iii) from the provider concerned, that he or she has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist; and".

Substitution of regulation 10 of the Regulations

10. The following regulation is hereby substituted for regulation 10 of the Regulations:

"**10.** A person who complies with the requirements in regulation 9 must be registered as a pharmacist intern and issued with a registration certificate by the registrar.".

Amendment of regulation 13 of the Regulations

11. The following regulation is hereby substituted for regulation 13 of the Regulations:

13. Requirements and conditions for registration as a pharmacist. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist, and —

(1) offered in the Republic may apply to the registrar for registration as a pharmacist: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 14;

(2) offered outside the Republic may apply to the registrar for registration as a pharmacist: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 17.

Amendment of regulation 14 of the Regulations

12. Regulation 14 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"14. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist, which is offered in the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist which is offered in the Republic, and who applies for registration as a pharmacist must—"

(b) the substitution for paragraph (1)*(b)* of the following paragraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and";

(c) the substitution for paragraphs (1)(c)(i) and 1(c)(ii) of the following paragraphs:

"(c)(i) he or she has successfully fulfilled the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist;

(ii) he or she has completed an internship: provided that the council may exempt him or her partially or in full from this requirement on submission of documentary evidence to the satisfaction of the council that he or she has undertaken practical training as part of his or her undergraduate studies under the supervision of a provider of an education and training programme approved by the council for purposes of registration as a pharmacist; and "

Amendment of regulation 15 of the Regulations

13. Regulation 15 of the Regulations is hereby amended by the substitution for the words preceding sub-regulation (1) of the following words:

"**15.** Any person who complies with the requirements in regulation 14 must be registered as a pharmacist and issued with a registration certificate by the registrar: Provided that any person registered as a pharmacist in terms of this regulation shall be entitled only to practise as such—";

Amendment of regulation 17 of the Regulations

14. Regulation 17 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"17. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist, which is offered outside the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist which is offered outside the Republic, and who applies for registration as a pharmacist must—"

(b) the substitution for paragraph *(b)* of sub-regulation (1) of the following paragraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;"

(c) the substitution for subparagraph (i) of paragraph *(c)* of sub-regulation (1) of the following subparagraph:

"(i) the qualification obtained outside the Republic which entitles him or her to practise as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated; ".

(d) the substitution for subparagraph (ii) of paragraph *(c)* of sub-regulation (1) of the following subparagraph:

"(ii) the fact that he or she is registered as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;".

Amendment of regulation 18 of the Regulations

15. Regulation 18 of the Regulations is hereby amended by the substitution for sub-regulation (1) of the following sub-regulation:

"(1) register the applicant in one of the categories of pharmacist's assistant under such conditions as the council may determine from time to time; or".

Amendment of regulation 23 of the Regulations

16. Regulation 23 of the Regulations is hereby amended by the substitution for sub-regulation (2) of the following sub-regulation:

"(2) submit acceptable documentary evidence to the registrar that he or she has satisfied all the requirements as published in regulations made in terms of the Act;".

Substitution of regulation 24 of the Regulations

17. The following regulation is hereby substituted for regulation 24 of the Regulations:

"**24.** A pharmacist who complies with the requirements of regulation 23 and applicable regulations relating to specialities must be registered as a specialist pharmacist and be issued with a registration certificate by the registrar, indicating his or her specialty.".

Substitution of regulation 28 of the Regulations

18. The following regulation is hereby substituted for regulation 28 of the Regulations:

"**Requirements and conditions for registration as a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic) or pharmacy technician (learner)**

28. Any person registered with a provider to undertake an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician must register with the council at the commencement of such learning programme: Provided

that no person will be registered with the council as a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic) or pharmacy technician (learner), as the case may be, unless he or she complies with the provisions of regulation 29.".

Amendment of regulation 29 of the Regulations

19. Regulation 29 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"**29.** Any person who applies for registration as a pharmacist's assistant in the category pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner) as the case may be, must –"

(b) the substitution for paragraph *(b)* of sub-regulation (1) of the following paragraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work or study permit as applicable, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and"; and

(c) the substitution for paragraph *(c)* of sub-regulation (1) of the following paragraph:

"*(c)* acceptable documentary evidence

(i) from the provider concerned that he or she has been registered for an education and training programme approved by the council for purposes of registration in the category pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician, as the case may be;

(ii) of approval by the council of the pharmacy where in-service training will be undertaken, and the tutor under whom the training will take place, where in-service training is a requirement of the

education and training programme referred to in subregulation 29(c)(i); and"

Substitution of regulation 30 of the Regulations

20. The following regulation is hereby substituted for regulation 30 of the Regulations:

"**30.** Any person who complies with the requirements of regulation 29 must be registered in the category pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner), as the case may be, and issued with a registration certificate by the registrar.".

Repeal of regulation 31 of the Regulations

21. Regulation 31 of the Regulations is hereby repealed.

Amendment of regulation 32 of the Regulations

22. Regulation 32 is hereby amended by-

(a) the substitution for sub-regulation 32 (1) of the following paragraph:

32. Removal from the register.— (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacist's assistants (learner basic), pharmacist's assistants (learner post-basic) or pharmacy technician (learner), as the case may be, the name of a pharmacist's assistant—

(a) who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a

pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician as the case may be;

(b) who no longer complies with the requirements and conditions for registration as a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner) as the case may be; or

(c) who is deceased.

Substitution of regulation 33 of the Regulations

23. The following regulation is hereby substituted for regulation 33 of the Regulations

33. Restoration to the register.—A pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner) as the case may be, whose name was removed from the register in terms of regulation 32 may, if applicable, have his or her name restored to the register by—

(1) submitting to the registrar:

(a) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council; and

(b) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted to an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician and".

(2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person

to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

Amendment to regulation 34 of the Regulations

24. The following regulation is hereby substituted for regulation 34 of the Regulations:

"**34. Requirements and conditions for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic).** Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), and —

(1) offered in the Republic may apply to the registrar for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 35;

(2) offered outside the Republic may apply to the registrar for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic): provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 37."

Amendment of regulation 35 of the Regulations

25. Regulation 35 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"35. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a

pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered in the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered in the Republic, and who applies for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) must—"

(b) the substitution for paragraph *(b)* of sub-regulation (1) of the following subparagraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;";

(c) the substitution for paragraph *(c)* of sub-regulation (1) of the following paragraph:

"*(c)* acceptable documentary evidence that he or she has successfully fulfilled the requirements of an education and training programme approved by the council for purposes of registration in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, and has completed any in-service training required; and".

Substitution of regulation 36 of the Regulations

26. The following regulation is hereby substituted for regulation 36 of the Regulations:

"**36.** Any person who complies with the requirements of regulation 35 must be registered as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, and issued with a registration certificate by the registrar.".

Amendment of regulation 37 of the Regulations

27. Regulation 37 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"37. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered outside the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered outside the Republic, and who applies for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) must—"

(b) the substitution for paragraph *(b)* of sub-regulation (1) of the following paragraph:

"*(b)* a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;";

(c) the substitution for subparagraph (i) of paragraph *(c)* of sub-regulation (1) of the following subparagraph:

"(i) the qualification obtained outside the Republic which entitles him or her to practise as a pharmacist's assistant in the country in which the institution or examining body that awarded such qualification is situated; ".

(d) the substitution for subparagraph (ii) of paragraph *(c)* of sub-regulation (1) of the following subparagraph:

"(ii) the fact that he or she is registered as a pharmacist's assistant in the country in which the institution or examining body that awarded such qualification is situated, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;".

Repeal of regulation 43 of the Regulations

28. Regulation 43 of the Regulations is hereby repealed.

Insertion of Chapter IXA and regulations 56A to 56R

29. The following Chapter and regulations are hereby inserted in the Regulations after regulation 56 of the Regulations:

"CHAPTER IXA

Requirements and conditions for registration as pharmacy technician (student)

56A. (1) Any person registered with a provider to undertake an education and training programme approved by the council for purposes of registration as a pharmacy technician, may register with the council as a pharmacy technician (student) at the commencement of the first year of study: Provided that no person shall be registered as a pharmacy technician (student) with the council unless he or she complies with the provisions of 56B.".

56B. Any person who applies for registration with the council as a pharmacy technician (student) must—

(a) submit to the registrar:

(i) a duly completed application on a form approved and provided by council;

(ii) a certified copy of his or her identity document or passport;

(iii) a certified copy of a study permit, in the case of a student who is not a South African citizen or a permanent resident in the Republic of South Africa; and

(iv) acceptable documentary evidence from the provider concerned that he or she has been admitted to the first or subsequent year of study of an education and training programme approved by the council for purposes of registration as a pharmacy technician; and

(b) pay the registration fee as determined by the council.

56C. Any person who complies with the requirements in regulation 56B must be registered as a pharmacy technician (student) and issued with a registration certificate by the registrar.

Removal from the register

56D. (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacy technician (students) the name of a student who—

(a) has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician;

(b) no longer complies with the requirements and conditions for registration as a pharmacy technician (student): Provided that a student who interrupts his or her studies may, on making written application annually to the registrar, have his or her name retained on the register of pharmacy technician (students) for a period

not exceeding one year from the end of the year in which he or she interrupts his or her studies; or

(c) is deceased.

(2) A person whose name has been removed as contemplated in sub-regulation (1)(a) and (b), must be notified of the removal, and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice is given.

Restoration to the register

56E. A pharmacy technician (student) whose name is removed from the register in terms of regulation 56D may, if applicable, have his or her name restored to the register—

(a) by submitting to the registrar—

(i) a duly completed application for restoration of his or her name to the relevant register on a form as approved and provided by the council; and

(ii) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted to an education and training programme approved by the council for purposes of registration as a pharmacy technician; and

(b) by paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register: Provided that if the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

Requirements and conditions for registration as pharmacy technician (trainee)

56F. Any person who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician, may register as a pharmacy technician (trainee) with the council: provided that no person may be registered as a pharmacy technician (trainee), unless he or she complies with regulation 56G.

56G. Any person who applies for registration as a pharmacy technician (trainee) must—

(a) submit to the registrar:

(i) a duly completed application on a form as approved and provided by council;

(ii) a certified copy of his or her identity document or passport;

(iii) a certified copy of a work permit, in the case of a person who is not a South African citizen or a permanent resident in the Republic of South Africa;

(iv) a duly completed and signed contract approved and provided by council for the undertaking of a traineeship; and

(v) acceptable documentary evidence—

(aa) of the approval by the council of the pharmacy where the traineeship will be undertaken;

(bb) of the registration of the tutor under whom such traineeship will take place;

(cc) from the provider concerned, that he or she has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician; and".

(b) pay the registration fee as determined by council.

56H. A person who complies with the requirements in regulation 56G must be registered as a pharmacy technician (trainee) and issued with a registration certificate by the registrar.

Removal from the register

56I. (1) Subject to sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacy technicians (trainee) the name of a pharmacy technician (trainee)—

(a) who has completed his or her traineeship to the satisfaction of the council;

(b) who has not completed his or her traineeship to the satisfaction of the council;

(c) who has discontinued his or her traineeship with the consent of the council;

(d) who no longer complies with the requirements and conditions for registration as a pharmacy technician (trainee); or

(e) who is deceased.

(2) A person whose name is removed in terms of sub-regulations (1)*(a)* to *(d)*, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice is given.

Restoration to the register

56J. A pharmacy technician (trainee) whose name is removed from the register in terms of regulation 56I, may, if applicable, have his or her name restored to the register—

(a) by submitting to the registrar—

(i) a duly completed application for restoration of his or her name to the register on a form as approved and provided by council;

(ii) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a pharmacy technician (trainee); and:

(iii) acceptable documentary evidence from a tutor to the effect that he or she has resumed his or her traineeship; and

(b) by paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register: Provided that if the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

Requirements and conditions for registration as pharmacy technician

56K. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician, and —

a) offered in the Republic may apply to the registrar for registration as a pharmacy technician: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 56L.

(b) offered outside the Republic may apply to the registrar for registration as a pharmacy technician: Provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 56N.

Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered in the Republic

56L. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered in the Republic, and who applies for registration as a pharmacy technician must—

(a) submit to the registrar:

(i) a duly completed application on a form approved and provided by council;

(ii) a certified copy of his or her identity document or passport;

(iii) a certified copy of a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;

(iv) evidence of successful fulfillment of the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician;

(v) proof of completion of a traineeship: provided that the council may exempt him or her partially or in full from this requirement on submission of documentary evidence to the satisfaction of the council that he or she has undertaken work based training under the supervision of a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician; and

(vi) acceptable documentary evidence that he or she has passed an examination or other evaluation as determined by council, if applicable; and

(b) pay the registration fee as determined by the council.

56M. A person who complies with the requirements of regulation 56L must be registered as a pharmacy technician and issued with a registration certificate by the registrar.

Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered outside the Republic

56N. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered outside the Republic, and who applies for registration as a pharmacy technician must—

(a) submit to the registrar:

(i) a duly completed application on a form as approved and provided by council;

(ii) a certified copy of—

(aa) his or her identity document or passport; and

(bb) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and

(iii) acceptable documentary evidence of—

(aa) the qualification obtained outside the Republic which entitles him or her to practise as a pharmacy technician in the country in which the institution or examining body that awarded such qualification is situated;

(bb) the fact that he or she is registered as a pharmacy technician in the country in which the institution or examining body that awarded such qualification is situated, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;

(cc) the fact that he or she is a fit and proper person and in good standing as a pharmacy technician with the relevant registration authority; and

(dd) the practical training which he or she has undertaken and completed, if any; and

(b) pay the registration fee as determined by council.

56O. (1) The registrar must submit an application that complies with the requirements of regulation 56N to the council for evaluation, and the council may—

(a) refuse to register the applicant as a pharmacy technician;

(b) register the applicant as a pharmacy technician; or

(c) register the applicant in any other category of pharmacist assistant.

(2) The council may prior to approving an application for registration in terms of sub-regulation (1)*(b)*, require that the applicant pass an examination or other evaluation determined by the council.

56P. A person registered in terms of regulation 56N must be issued with a registration certificate by the registrar.

Removal from the register

56Q. (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register the name of a pharmacy technician—

(a) who no longer complies with the requirements and conditions for registration as a pharmacy technician; or

(b) who is deceased.

(2) A pharmacy technician whose name is removed in terms of sub-regulation (1)*(a)*, must be notified of such removal and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice is given.

Restoration to the register

56R. A pharmacy technician whose name is removed from the register in terms of regulation 56Q may, if applicable, have his or her name restored to the register—

(a) by submitting to the registrar:

(i) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council;

(ii) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a pharmacy technician; and

(b) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register: Provided that if the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.".

Substitution of regulation 71 of the Regulations

30. The following regulation is hereby substituted for regulation 71 of the Regulations:

"**71.** The council may inspect premises in which the business of a pharmacy is carried out and may provide the pharmacy owner or the responsible pharmacist with a written report of the findings of such inspection, if it is found that such pharmacy does not comply with the prescribed requirements or is, in the opinion of the council, unsuitable for the conduct of a pharmacy business.".

Substitution of regulation 91 of the Regulations

32. The following regulation is hereby substituted for regulation 91 of the Regulations:

"**Requirements and conditions for registration of providers of pharmacy education and training**

91. Only providers who comply with the minimum criteria for the approval of providers of pharmacy education and training as determined and published by council, shall be entitled to offer pharmacy education and training for purposes of registration as a pharmacist, pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician, registration of a speciality, continuing professional development, supplementary training or courses determined by the Council in terms of the Medicines Act;";

Insertion of regulation 91A

33. The following regulation is hereby inserted after regulation 91 of the Regulations:

"**91A.** No person or provider shall offer any education and training using the words "pharmacy", "pharmacist", "pharmaceutical" or any such other words which may imply the profession of pharmacy or pharmacy support personnel, unless such provider has been registered and such education and training have been approved by council.".

Substitution of regulation 96 of the Regulations

34. The following regulation is hereby substituted for regulation 96 of the Regulations:

"**96.** Any pharmacist approved by the council as an assessor of pharmacy education and training must register with the council: Provided that no person must be registered as an assessor unless he or she complies with the provisions of regulation 97.".

Substitution of regulation 98 of the Regulations

35. The following regulation is hereby substituted for regulation 98 of the Regulations

"98. An assessor who complies with the requirements of regulation 97 must be issued with a registration certificate by the registrar, subject to such conditions as may be determined by council.".

Short Title

36. These Regulations are called the Amendment Regulations relating to the Registration of persons and the maintenance of registers, 2020 and are published for comment.

TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS REGULATIONS RELATING TO THE REGISTRATION OF PERSONS AND THE MAINTENANCE OF REGISTERS, MADE IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974)

Name of Organisation / Individual:	
Date of submission:	

Comment no.	**Regulation, subregulation or paragraph**			**Comment and Rationale**	**Proposed Revised Text** **Bold underlined** – additions **[square brackets bold]** – deletions
	Reg	**Subreg**	**Par.**		
Example 1	*4*	*(1)*	*(a)(i)*	*Provide a rationale for the comment.*	*Provide a revised text example.*

ADD MORE ROWS TO TABLE AS REQUIRED

DEPARTMENT OF HEALTH

NO. 657 **12 JUNE 2020**

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO THE PRACTICE OF PHARMACY: AMENDMENT REGULATIONS, 2019

The Minister of Health intends, in consultation with the South African Pharmacy Council, in terms of section 49(1)*(a)* and (3), read with section 35A of the Pharmacy Act, 1974 (Act No. 53 of 1974), to make the regulations in the Schedule.

The proposed amendments to these Regulations enable:

a) the establishment of a new category of pharmacy support personnel – pharmacy technician – with a new scope of practice;
b) the categorisation of pharmacy technicians as a type of pharmacist's assistant to enable these persons to handle medicines in accordance with the provisions of the Medicines and Related Substances Act, 1965, (Act 101 of 1965);
c) the retention of the categories of pharmacy support personnel - pharmacist's assistants (basic) and pharmacist's assistants (post-basic) - with amendments to the scope of practice;
d) two routes for the education and training and subsequent registration of pharmacy technicians – one via the Occupational Qualifications Sub-framework (OQSF), and the other via the Higher Education Qualifications Sub-framework (HEQSF);
e) registration of persons undertaking a pharmacy technician qualification which falls under the HEQSF, as a pharmacy technician (student) and completion of a traineeship whilst registered as a pharmacy technician (trainee);
f) registration of persons undertaking a pharmacy technician qualification which falls under the OQSF as a pharmacy technician (learner) and the option to exit as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) after completion of part

qualifications. NOTE: There is no traineeship or internship required after completing these part-qualifications or the whole qualification;

g) upskilling of current pharmacist's assistants, whilst enabling those who are unable to undergo further education and training to continue to practise in the category in which they are registered.

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

Any person wishing to comment on or make representation with regard to the proposed amendments to the Regulations is hereby invited to do so within three (3) months of the date of publication of this notice.

All such comments and representations must be submitted in writing using the format outlined in the attached template (available on www.health.gov.za), marked for the attention of Ms Mihloti Mushwana, Director: Public Entities Governance in any one of the following ways:

(a) Hand delivered to:
Director-General: Health
National Department of Health
222 Thabo Sehume Street
Pretoria
0001

(b) By electronic mail: regulationcomments@health.gov.za

Comments received after the closing date may not be considered. Enquiries may be made to Mandie Bhembe on (012) 395 8288/8130 or regulationcomments@health.gov.za.

DR. ZWELINI LAWRENCE MKHIZE, MP
MINISTER OF HEALTH
DATE 24/03/2020

TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS RELATING TO THE PRACTICE OF PHARMACY MADE IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974)

Name of Organisation / Individual:	
Date of submission:	

Comment no.	**Regulation, subregulation or paragraph**			**Comment and Rationale**	**Proposed Revised Text** **Bold underlined** – additions **[square brackets bold]** – deletions
	Reg	**Subreg**	**Par.**		
Example 1	*4*	*(1)*	*(a)(i)*	*Provide a rationale for the comment.*	*Provide a revised text example.*

ADD MORE ROWS TO TABLE AS REQUIRED

SCHEDULE

GENERAL EXPLANATORY NOTE:

_____ Words underlined with a solid line indicate insertions in existing enactments.

Definitions

1. In this Schedule, the "Regulations" means the Regulations Relating to the Practice of Pharmacy, published under Government Notice No. R.1158 of 20 November 2000.

Amendment of regulation 1 of Regulations

2. Regulation 1 of the Regulations is hereby amended by—

(a) the substitution for the definition of "direct personal supervision" of the following definition:

" **'direct personal supervision'** means guidance and support provided by a pharmacist whilst physically present in a pharmacy, in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;";

(b) the substitution for the definition of "indirect personal supervision" of the following definition:

" **'indirect personal supervision'** means guidance and support provided by a pharmacist to pharmacy support personnel in a primary health care clinic or any other facility as approved by the council, in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;";

(c) the insertion after the definition of "indirect personal supervision" of the following definition:

" **'in-service training'** means the training undertaken by a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic) under the direct

personal supervision of a tutor at a pharmacy approved by the council for purposes of such training;";

(d) substitution of the definition of "pharmacist's assistant" with the following definition:

'" **pharmacist's assistant"** means a person registered in one of the following categories:

(*a*) pharmacist's assistant (learner basic);

(*b*) pharmacist's assistant (basic);

(*c*) pharmacist's assistant (learner post-basic);

(*d*) pharmacist's assistant (post-basic);

(e) pharmacy technician (learner)

(f) pharmacy technician (student);

(*g*) pharmacy technician (trainee);

(*h*) pharmacy technician;

(*i*) pharmacy student;'

which constitute the various categories of pharmacy support personnel registered as such in terms of the Act';

(e) the insertion after the definition of "pharmacy student" of the following definitions:

" **'pharmacy technician'** means a person registered as such in terms of the Act;

'pharmacy technician (learner)' means a natural person registered as such in terms of the Act;

'pharmacy technician (student)' means a natural person registered as such in terms of the Act;

'pharmacy technician (trainee)' means a natural person registered as such in terms of the Act;"

(f) the substitution for the definition of "primary care drug therapy" of the following definition:

" **'primary care drug therapy'** means diagnosing a health need, prescribing and supplying of medicine to meet the health need of a patient or group of patients or, where necessary, the referral to another health care professional by a pharmacist who has received the necessary authorisation from the council and is the holder of a permit issued in terms of the Medicines Act;";

(g) the insertion after the definition of "private health facility" of the following definition:

" **'provider'** means any person or institution approved by and registered with the council in terms of the Act to provide education and training approved by the council for purposes of:

(a) registration as a pharmacist;

(b) registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician;

(c) registration of a speciality;

(d) continuing professional development;

(c) supplementary training; or

a course determined by the Council in terms of the Medicines Act;";

(h) the deletion of the definition of "qualification in pharmacy" after the definition of "public health facility"

(i) the insertion after the definition of "sell" of the following definitions:

" **'traineeship'** means practical training, as determined by the council from time to time, undertaken by a pharmacy technician (trainee) in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by the council in terms of the Act for purposes of such training;";

" **'tutor'** means a pharmacist registered with the council as a tutor, to supervise the internship of a pharmacist intern, the traineeship of a pharmacy technician (trainee)

or the in-service training of a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic);"; and

(j) the insertion after the definition of "wholesale pharmacy" of the following definition:

" **'work-based training'** means education and training undertaken by a pharmacist's assistant (learner basic); pharmacist's assistant (learner post-basic), or pharmacy technician (learner) in a pharmacy under the auspices of a provider, as part of an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic); pharmacist's assistant (post-basic), or pharmacy technician. ".

Substitution of regulation 2 of Regulations

3. The following regulation is hereby substituted for regulation 2 of the Regulations:

"**2. Conditions under which services or acts must be provided or performed**

The services or acts pertaining to the scope of practice of persons registered in terms of the Act must be provided or performed in accordance with the Act and the Medicines Act.".

Amendment of regulation 4

4. Regulation 4 of the Regulations is hereby amended by the substitution for subregulation (1) of the following subregulation:

"(1) the acts specifically pertaining to the profession of a pharmacist as prescribed in regulation 3

Substitution of regulation 5 of Regulations

5. The following regulation is hereby substituted for regulation 5 of the Regulations:

"**5. Scope of practice of a pharmacist intern**

A pharmacist intern may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacy technician under the direct personal supervision of a pharmacist.".

Substitution of regulation 7 of Regulations

6. The following regulation is hereby substituted for regulation 7 of the Regulations:

"**7. Scope of practice of a pharmacy student**

(1) A pharmacy student who has successfully completed—

(a) the first year of an education and training programme approved by the council for purposes of registration as a pharmacist, and who is undergoing his or her second year of study may perform services or acts pertaining to the scope of practice of a pharmacist's assistant (basic);

(b) the second year of an education and training programme approved by the council for purposes of registration as a pharmacist, and who is undergoing his or her third year of study, may perform services or acts pertaining to the scope of practice of a pharmacist's assistant (post-basic);

(c) the third or subsequent year of an education and training programme approved by the council for purposes of registration

as a pharmacist, and who is undergoing his or her fourth or subsequent year of study may perform services or acts pertaining to the scope of practice of a pharmacy technician.

(2) The services or acts contemplated in subregulation (1) may only be performed under the direct personal supervision of a pharmacist in a pharmacy.".

Substitution of regulation 8 of Regulations

7. The following regulation is hereby substituted for regulation 8 of the Regulations:

8.(1) A pharmacy student may for purposes of education and training, and under the auspices of a provider approved by the council to offer education and training for purposes of registration as a pharmacist and with whom such student is enrolled, provide the services or perform the acts prescribed in regulation 4 under the direct personal supervision of a pharmacist in a pharmacy;

(2) The services or acts referred to in subregulation 8(1) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.

Amendment of regulation 9 of Regulations

8. Regulation 9 of the Regulations is hereby amended by—

(a) the deletion of subregulation (1); and

(b) the substitution for subregulation (5) of the following subregulation:

"(5) the distribution and control of stock of Schedule 1 to Schedule 5 medicines or scheduled substances; and".

Substitution of regulation 10 of the Regulations

9. The following regulation is hereby substituted for regulation 10 of the Regulations:

"**10. Pharmacist's assistant (learner basic)**

(1) A pharmacist's assistant (learner basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) and who is undertaking in-service training, may provide the services or perform the acts prescribed in regulation 9 under the direct personal supervision of a pharmacist in a pharmacy.

(2) A pharmacist assistant (learner basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician and who is undertaking work-based training, may provide the services or perform the acts prescribed in regulation 9 under the direct personal supervision of a pharmacist in a pharmacy.

(3) The services or acts referred to in subregulations 10(1) and 10(2) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act."

Amendment of regulation 11 of Regulations

10. Regulation 11 of the Regulations is hereby amended by the substitution for subregulations (5) and (6) of the following subregulations:

"(5) the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances;

(6) the ordering of medicine and scheduled substances up to and including Schedule 6 according to an instruction of a person authorised in terms of the Medicines Act to purchase or obtain such medicine or scheduled substance;".

Substitution of regulation 13 of the Regulations

11. The following regulation is hereby substituted for regulation 13 of the Regulations:

"13. Pharmacist assistant (learner post-basic)

(1) A pharmacist's assistant (learner post-basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (post-basic) and who is undertaking in-service training, may provide the services or perform the acts prescribed in regulation 11 under the direct personal supervision of a pharmacist in a pharmacy.

(2) A pharmacist assistant (learner post-basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician and who is undertaking work-based training, may provide the services or perform the acts prescribed in regulation 11 under the direct personal supervision of a pharmacist in a pharmacy.

(3) The acts referred to in subregulations 13(1) and 13(2) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.

(4) A pharmacist assistant (learner post-basic), may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant (basic) under the direct personal supervision of a pharmacist in a pharmacy."

Insertion of regulations 13A to 13D in Regulations

12. The following regulations are hereby inserted after regulation 13 of the Regulations:

"13A. Pharmacy technician

(1) Subject to subregulation (3), a pharmacy technician may provide or perform the following services or acts under the direct personal supervision of a pharmacist:

(a) Assist with the manufacturing, compounding, manipulation or preparation of a non-sterile or sterile medicine or scheduled substance, in accordance with the Medicines Act, by performing the following functions:

(i) The weighing of materials including schedule 1 to 6 substances;

(ii) the checking and signing of the addition of materials to the mix after the pharmacist has checked each mass or volume and signed for each dispensed material in accordance with the Batch Manufacturing Document or prescription and in compliance with standard operating procedures;

(iii) checking the identity of the bulk product and its identity label after the pharmacist has checked and signed in accordance with the Batch Manufacturing Document or prescription and in compliance with standard operating procedures;

(iv) the start-up line clearance and opening of the line as per documented procedure and detailed checklist: Provided that the pharmacist has provided the necessary signed authorisation therefor;

(v) in-process control during the manufacture of Schedule 0 to 6 medicine or scheduled substances: Provided that the pharmacist does periodic checks in accordance with standard operating procedures and that final line closure is signed off by the pharmacist; and

(vi) the reconciliation of documents of Schedule 0 to 6 medicine or scheduled substances: Provided that the final release of the product is performed by a pharmacist;

(b) the packaging and re-packaging of Schedule 0 to Schedule 6 medicine or scheduled substances, in accordance with the Medicines Act, including--

(i) checking and signing the identity of the bulk product and printed packaging material in accordance with the Batch Manufacturing Document and in compliance with standard operating procedures;

(ii) start-up line clearance and opening of the packaging line in accordance with standard operating procedures and detailed checklist: Provided that the pharmacist has provided the necessary signed authorisation therefor; and

(iii) in-process control during packaging and re-packaging of Schedule 0 to Schedule 6 medicines or scheduled substances: Provided that the pharmacist does periodic checks in accordance with standard operating procedures and that final line closure is signed off by the pharmacist;

(c) the sampling, or supervision of the sampling of medicines or scheduled substances in accordance with good manufacturing practice as determined in terms of the Medicines Act;

(d) picking, packing and despatch of orders for Schedule 1 to Schedule 6 medicine or scheduled substances: Provided that orders that contain Schedule 6 medicine are validated by a pharmacist prior to release thereof;

(e) the checking of orders containing Schedule 1 to Schedule 6 medicine in closed packs, prior to the packing and dispatch thereof, which have been picked by a pharmacist's assistant, as well as the supervision of such persons: Provided that this function may only be performed in a manufacturing pharmacy, wholesale pharmacy or bulk store of an institutional pharmacy;

(f) assisting with the management of stock of Schedule 1 to Schedule 6 medicine or scheduled substances: Provided that orders that contain medicine which fall into Schedule 5 and Schedule 6 are validated by a pharmacist;

(g) the ordering and receipt of Schedule 1 to Schedule 6 medicine or scheduled substances: Provided that orders that contain Schedule 5 and Schedule 6 medicine are validated by a pharmacist;

(h) the sale of Schedule 1 and Schedule 2 medicine without the prescription of an authorised prescriber: Provided that the supply of a Schedule 2 medicine takes place in consultation with a pharmacist;

(i) the dispensing of Schedule 1 to Schedule 6 medicine or scheduled substances (i.e. the selection, manipulation or compounding of the medicine, the labelling and packing of the medicine in an appropriate container and the provision of information to a patient, caregiver or the agent of a patient regarding the correct use of the medicine to optimise therapeutic outcomes) on the prescription of an authorised prescriber: Provided that the pharmacist interprets and evaluates the prescription;

(j) general housekeeping and administrative tasks in the pharmacy as specified by the responsible pharmacist;

(k) supervision of other pharmacist's assistants, as specified by the responsible pharmacist; and

(l) the provision of technical support in the provision of screening tests: provided that where an interpretation of results is required, this is done by a pharmacist;

(2) Subject to subregulation (3), a pharmacy technician may provide or perform the following services or acts under the supervision of a pharmacist who may not be physically present in a primary health care clinic or other facility as approved by the council:

(a) The ordering of Schedule 1 to Schedule 6 medicines or scheduled substances: Provided that orders that contain Schedule 6 are validated by a pharmacist;

(b) the receipt and management of stock of Schedule 1 to Schedule 6 medicines or scheduled substances: Provided that orders received that contain Schedule 6 are validated by a pharmacist;

(c) receive and screen prescriptions for medicine which appears on the national Primary Health Care Essential Medicines List and which is prescribed in accordance with Standard Treatment Guidelines;

(d) the selection, manipulation or compounding of medicine prescribed, the labelling and packing of the medicine in an appropriate container;

(e) the provision of information to a patient, caregiver or the agent of a patient about medicine dispensed;

(f) the provision of information to a patient, caregiver or the agent of a patient about medicines which have been dispensed at a pharmacy and sent to the primary health care clinic or other facility, as approved by Council for supply to the patient or the patient's agent or caregiver;

(g) management of a dispensary or medicine room in a primary health care clinic in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act; and

(h) general housekeeping and administrative tasks as specified by the supervising pharmacist.

(3) The services or acts referred to in subregulations (1) and (2) must be performed in accordance with the Act, the rules relating to good pharmacy practice published in terms of section 35A of the Act, the Medicines Act and where applicable, good manufacturing or distribution practice, as determined in terms of the Medicines Act.

13B Pharmacy technician (learner)

(1) A pharmacy technician (learner) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician and who is undertaking work-based training, may provide the services or perform the acts prescribed in regulation 13A under the direct personal supervision of a pharmacist in a pharmacy.

(2) The acts referred to in subregulation 13B(1) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.

(3) A pharmacy technician (learner) may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist in a pharmacy

13C. Pharmacy technician (student)

(1) A pharmacy technician (student) may, for purposes of education and training, and under the auspices of a provider of an education and training programme, approved by council for purposes of registration as a pharmacy technician, and with whom such student is enrolled, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacy technician under the direct personal supervision of a pharmacist.

(2) The services or acts referred to in subregulation 13C(1) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.

(3) A pharmacy technician (student) may, after successful completion of the first year of study, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant (basic) under the direct personal supervision of a pharmacist in a pharmacy.

13D. Pharmacy technician (trainee)

(1) A pharmacy technician (trainee) may for purposes of education and training, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacy technician under the direct personal supervision of a tutor.

(2) The services or acts contemplated in subregulation (1) may only be performed by a pharmacy technician (trainee) as part of a traineeship."

(3) A pharmacy technician (trainee) may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist.".

Substitution of regulation 14 of Regulations

13. Regulation 14 is hereby amended by the substitution for regulation 14 of the following regulation:

"**14. Supervision of pharmacy support personnel and pharmacist interns**

(1) A pharmacist may have a maximum of five pharmacy support personnel under his or her supervision: Provided that--

(a) the pharmacist has no more than three pharmacist's assistants (learner basic), pharmacist's assistants (learner post-basic), pharmacy technicians (learner), or pharmacy technicians (trainee) under direct supervision; and

(b) a pharmacist who is the tutor to a pharmacist intern may have a maximum of four pharmacy support personnel under his or her supervision, of which only two may be pharmacist's assistants (learner basic), pharmacist's assistants (learner post-basic), pharmacy technicians (learner), or pharmacy technicians (trainee) .

(2) A pharmacist who is a tutor of a pharmacist intern undergoing an internship at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, may act as tutor to a maximum of five such interns and no pharmacy support personnel.".

Short Title

14. These Regulations are called the Amendment regulations relating to the practice of pharmacy, 2019 and are published for comment.

DEPARTMENT OF HEALTH

NO. 658 **12 JUNE 2020**

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO PHARMACY EDUCATION AND TRAINING: AMENDMENT REGULATIONS, 2019

The Minister of Health intends, in consultation with the South African Pharmacy Council, in terms of sections 33 and 49 of the Pharmacy Act, 1974 (Act No. 53 of 1974), to make the regulations in the Schedule.

The proposed amendments to these Regulations enable:

a) the establishment of a new category of pharmacy support personnel – pharmacy technician – with a new scope of practice;
b) the categorisation of pharmacy technicians as a type of pharmacist's assistant to enable these persons to handle medicines in accordance with the provisions of the Medicines and Related Substances Act, 1965, (Act 101 of 1965);
c) the retention of the categories of pharmacy support personnel - pharmacist's assistants (basic) and pharmacist's assistants (post-basic) - with amendments to the scope of practice;
d) two routes for the education and training and subsequent registration of pharmacy technicians – one via the Occupational Qualifications Sub-framework (OQSF), and the other via the Higher Education Qualifications Sub-framework (HEQSF);
e) registration of persons undertaking a pharmacy technician qualification which falls under the HEQSF, as a pharmacy technician (student) and completion of a traineeship whilst registered as a pharmacy technician (trainee);

f) registration of persons undertaking a pharmacy technician qualification which falls under the OQSF as a pharmacy technician (learner) and the option to exit as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) after completion of part qualifications. NOTE: There is no traineeship or internship required after completing these part-qualifications or the whole qualification;

g) upskilling of current pharmacist's assistants, whilst enabling those who are unable to undergo further education and training to continue to practise in the category in which they are registered.

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

Any person wishing to comment on or make representation with regard to the proposed amendments to the Regulations is hereby invited to do so within three (3) months of the date of publication of this notice.

All such comments and representations must be submitted in writing using the format outlined in the attached template (available on www.health.gov.za), marked for the attention of Ms Mihloti Mushwana, Director: Public Entities Governance in any one of the following ways:

(a) By electronic mail: regulationcomments@health.gov.za

(b) Hand delivered to:
Director-General: Health
National Department of Health
222 Thabo Sehume Street
Pretoria
0001

Comments received after the closing date may not be considered. Enquiries may be made to Mandie Bhembe on (012) 395 8288/8130 or regulationcomments@health.gov.za.

DR. ZWELINI LAWRENCE MKHIZE, MP
MINISTER OF HEALTH
DATE 24/03/2020

TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS RELATING TO PHARMACY EDUCATION AND TRAINING MADE IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974)

Name of Organisation / Individual:	
Date of submission:	

Comment no.	**Regulation, subregulation or paragraph**			**Comment and Rationale**	**Proposed Revised Text** **Bold underlined** – additions **[square brackets bold]** – deletions
	Reg	**Subreg**	**Par.**		
Example 1	*4*	*(1)*	*(a)(i)*	*Provide a rationale for the comment.*	*Provide a revised text example.*

ADD MORE ROWS TO TABLE AS REQUIRED

GENERAL EXPLANATORY NOTE:

_____ Words underlined with a solid line indicate insertions in existing enactments.

SCHEDULE

Definition

1. In this Schedule the "Regulations" means the Regulations Relating to Pharmacy Education and Training, published under Government Notice No. R. 1156 of 20 November 2000, as corrected by Government Notice No. R. 1321 of 8 December 2000.

Amendment of regulation 1 of Regulations

2. Regulation 1 of the Regulations is hereby amended by—

(a) the deletion of the definition of "certificate of qualification" after the definition of "certificate of approval"

(b) the substitution for the definition of "continuing professional development" of the following definition:

"continuing professional development" means the process by which persons registered under this Act maintain and enhance their competence throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training;

(c) the substitution for the definition of "contract" of the following definition:

"'**contract**' means a written contract approved by the council which lays down the conditions of the —

(a) internship of a pharmacist intern;

(b) in-service training of a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic); or

(c) traineeship of a pharmacy technician (trainee);"

(d) the substitution for the definition of "direct personal supervision" of the following definition:

"'**direct personal supervision**' means guidance and support provided by a pharmacist whilst physically present in a pharmacy, in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;";

(e) substitution for the definition of "pharmacist's assistant" of the following definition:

"**pharmacist's assistant**" means a natural person registered in one of the following categories:

(a) pharmacist's assistant (learner basic);

(b) pharmacist's assistant (basic);

(c) pharmacist's assistant (learner post-basic);

(d) pharmacist's assistant (post-basic);

(e) pharmacy technician (learner);

(f) pharmacy technician (student);

(g) pharmacy technician (trainee);

(h) pharmacy technician; or

(i) pharmacy student;

which constitute the various categories of pharmacy support personnel registered as such in terms of the Act';

(f) the insertion after the definition of "pharmacist's assistant" of the following definitions:

" '**pharmacy technician**' means a person registered as such in terms of the Act;

'**pharmacy technician (learner)**' means a person registered as such in terms of the Act;

'**pharmacy technician (student)**' means a person registered as such in terms of the Act;

'**pharmacy technician (trainee)**' means a person registered as such in terms of the Act;";

(g) the substitution for the definition of "provider" of the following definition:

" '**provider**' means any person or institution approved by and registered with the council in terms of the Act to provide education and training approved by the council for purposes of:

(a) registration as a pharmacist;

(b) registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician;

(c) registration of a speciality;

(d) continuing professional development;

(e) supplementary training; or

a course determined by the Council in terms of the Medicines Act;";

(h) the deletion of the definition of "qualification in pharmacy" after the definition of public health facility;

(i) the insertion after the definition of "supplementary training" of the following definition:

" **'traineeship'** means practical training, as determined by the council from time to time, undertaken by a pharmacy technician (trainee) in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by the council in terms of the Act for purposes of such training;";

(j) the substitution for the definition of "tutor" of the following definition:

"**'tutor'** means a pharmacist registered with the council as a tutor, to supervise the internship of a pharmacist intern, the traineeship of a pharmacy technician (trainee) or the in-service training of a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic);";

(k) the deletion of the definition of "unit standards" after the definition of "tutor"

(l) the insertion after the definition of "wholesale pharmacy" of the following definition:

" **'work-based training'** means education and training undertaken by a pharmacist's assistant (learner basic); pharmacist's assistant (learner post-basic), or pharmacy technician (learner) in a pharmacy under the auspices of a provider, as part of an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic); pharmacist's assistant (post-basic), or pharmacy technician. ".

Substitution of regulation 2 of Regulations

3. The following regulation is hereby substituted for regulation 2 of the Regulations:

"**2.** Education and training programmes for purposes of registration as a pharmacist shall be approved by the council."

Substitution of regulation 3 of Regulations

4. The following regulation is hereby substituted for regulation 3 of the Regulations:

"3. Only a provider that holds a certificate of approval for an education and training programme approved for purposes of registration as a pharmacist may provide such education and training "

Substitution of regulation 4 of Regulations

5. The following regulation is hereby substituted for regulation 4 of the Regulations:

4. An education and training programme approved by the council for purposes of registration as a pharmacist must extend over a minimum period of four years: provided that if such programme includes practical training to the satisfaction of the council of not less than one year or periods of not less than one year in the aggregate, as part of the undergraduate studies, under the supervision of the provider concerned, such programme must extend over a minimum period of five years.

Insertion of new Chapter II

6. The following new Chapter II is hereby inserted after regulation 4 of the Regulations:

"CHAPTER II

Substitution of regulation 5 of Regulations

7. The following regulation is hereby substituted for regulation 5 of the Regulations:

Requirements and conditions for pharmacy internship

5.(1) A person who has completed an education and training programme approved by the council for purposes of registration as a pharmacist must, prior to registration as a pharmacist, undertake an internship in accordance with this Chapter for a period or aggregate period specified in subregulation (3);

(2) The council may exempt a person referred to in subregulation (1), partially or in full, from the requirement of subregulation (1) on submission of documentary evidence to the satisfaction of the council that the person has undertaken other relevant practical training for a period or aggregate period equivalent to the period specified in subregulation (3).

(3) The period of internship contemplated in subregulation (1) must be for a period or aggregate period of at least 12 months.

Substitution of regulation 6 of Regulations

8. The following regulation is hereby substituted for regulation 6 of the Regulations:

6. The internship contemplated in regulation 5 must be undertaken—

(a) in terms of a contract;

(b) under the direct personal supervision of a tutor;

(c) in a community pharmacy, institutional pharmacy, manufacturing pharmacy, or wholesale pharmacy which provides a minimum number of services pertaining to the scope of practice of a pharmacist as may be determined by the council in terms of the Act, and which is approved by the council in terms of the Act for purposes of such training; or

(d) at a provider who holds a certificate of approval for an education and training programme approved by the council for purposes of registration as a pharmacist.

Substitution of regulation 7 of Regulations

9. The following regulation is hereby substituted for regulation 7 of the Regulations:

7. No person may commence an internship unless—

(a) such person has been registered as a pharmacist intern in terms of the Act;

(b) a contract has been entered into between the pharmacist intern and the tutor concerned;

(c) the pharmacy or provider at which the internship will take place has been approved by the council in terms of section 34 of the Act; and

(d) the tutor has been registered as such.

Substitution of regulation 8 of Regulations

10. The following regulation is hereby substituted for regulation 8 of the Regulations:

8. No pharmacist, pharmacy or provider of an education and training programme approved by the council for purposes of registration as a pharmacist, may employ any person as a pharmacist intern or in any other capacity which may imply or lead such person to believe that he or she is undertaking an internship, unless the requirements in regulations 6 and 7 have been complied with.

11. Deletion of regulation 9 of Regulations

Regulation 9 of the Regulations is hereby deleted

Substitution of regulation 10 of Regulations

12. The following regulation is hereby substituted for regulation 10 of the Regulations:

10. An internship undertaken at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, or in a manufacturing pharmacy or a wholesale pharmacy, must include a period of not less than 400 hours of practical training at a community or institutional pharmacy approved by the council for such training in terms of the Act: Provided that—

(a) the tutor, referred to in regulation 6(b), must—

(i) make arrangements for the keeping of the necessary records of such training; and

(ii) inform the council of the community or institutional pharmacy where the practical training will be undertaken;

(b) such periods of practical training must be undertaken on the basis of periods, each of which must be at least five consecutive days;

(c) there is a tutor at the pharmacy where practical training is undertaken who must keep records of such training;

(d) the responsibilities of all the parties regarding such practical training must be clearly documented and included in the internship contract.

Substitution of regulation 11 of Regulations

13. The following regulation is hereby substituted for regulation 11 of the Regulations:

11. No internship undertaken at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist may be recognised in terms of the Act, unless the prospective tutor has submitted to the registrar—

(a) full particulars of the proposed post-graduate study or research to be undertaken by the prospective intern and the post-graduate study or research has been approved by the council in terms of the Act; and

(b) documentary evidence that the prospective intern is registered at such provider for the post-graduate study or research referred to in subregulation *(a)*.

Substitution of regulation 12 of Regulations

14. The following regulation is hereby substituted for regulation 12 of the Regulations:

12. If an intern undergoing an internship at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, contemplated in regulation 11, discontinues his or her studies or research for any reason, or ceases to be registered at that provider, he or she must receive recognition only for the period of practical training duly completed at a community or institutional pharmacy referred to in regulation 10.

Substitution of regulation 13 of Regulations

15. The following regulation is hereby substituted for regulation 13 of the Regulations:

13. The internship of a pharmacist intern at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, must be regarded as completed upon successful completion of the required period of practical training referred to

in regulation 10 and the submission of documentary evidence to the registrar that the intern has satisfied the requirements of the provider for the awarding of at least a master's degree.

Substitution of regulation 14 of Regulations

16. The following regulation is hereby substituted for regulation 14 of the Regulations:

Cession of contract of pharmacy internship

14. A contract contemplated in regulation 6*(a)* may be ceded in the event of—

(a) the death of a tutor, his or her conviction of a serious offence or suspension or removal of his or her name from the register of pharmacists during the contract;

(b) the discontinuation of practice of the tutor or the resignation of the tutor from the pharmacy or provider approved for the internship;

(c) the closure of the pharmacy or provider approved for the internship;

(d) mutual consent of the tutor and the pharmacist intern for a reason which is acceptable to the registrar; or

(e) any other reason the registrar may consider to be acceptable:

Provided that the period of internship undertaken by the pharmacist intern under the original tutor must be recognised by the council for the purposes of internship and the prospective tutor accepts the delegation of the rights, obligations and interests in terms of such a contract.

Substitution of regulation 15 of Regulations

17. The following regulation is hereby substituted for regulation 15 of the Regulations:

Approval of contract of cession

15. (1) A pharmacist intern intending to cede a contract to another tutor must, at least seven days before such cession occurs, submit to the registrar—

(a) a duly completed application on a form, as approved and provided by the council;

(b) a duly completed and signed contract of cession for the conducting of an internship approved and provided by the council;

(c) documentary evidence—

(i) of the approval by the council of the pharmacy or provider where the internship of the pharmacist intern will occur after cession of the contract;

(ii) of the registration with the council of the tutor under whose direct personal supervision such internship will take place;

(iii) where applicable, that he or she is registered at an institution approved as a provider of a course of study which will lead to the awarding of at least a master's degree; and

(iv) an affidavit by the previous tutor, where possible, affirming that partial internship was successfully performed.

(2) The pharmacist intern contemplated in subregulation (1) must pay the cession fee as may be determined by the council in terms of the Act.

Substitution of regulation 16 of Regulations

18. The following regulation is hereby substituted for regulation 16 of the Regulations:

Delegation of training by tutor

16.(1) Subject to subregulations (2), (4) and (5), a pharmacist may not act as a tutor to more than one pharmacist intern at the same time.

(2) A tutor practising in a pharmacy where other pharmacists practise on a full-time basis may act as tutor to more than one pharmacist intern, in which event, the tutor may delegate the actual practical training of all such additional pharmacist interns to such other pharmacists, subject to subregulation (3).

(3) In the event of subregulation (2)—

(a) there must be one pharmacist for each additional pharmacist intern;

(b) the tutor may not delegate the training of more than four pharmacist interns;

(c) the responsibility for the internship of all such pharmacist interns must remain with the tutor;

(d) the tutor must inform the council, in writing, of a delegation or of any changes to such delegation; and

(e) the internship must be conducted in accordance with the provisions of these Regulations.

(4) A tutor may act as tutor to a second pharmacist intern when the pharmacist intern already under training with such tutor has completed his or her ninth month of internship.

(5) A tutor at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, may, with the prior approval of the registrar, act as a tutor to no more than five pharmacist interns at the same time.

Substitution of regulation 17 of Regulations

19. The following regulation is hereby substituted for regulation 17 of the Regulations:

Assessment and completion of pharmacist internship

17. The tutor of a pharmacist intern must submit to the registrar—

(*a*) assessment forms, obtainable from the council, on the progress of the pharmacist intern during the period of internship; and

(*b*) an affidavit, at the end of the period of internship, affirming that—

(i) the training has been completed satisfactorily in accordance with council's requirements for internship;

(ii) the pharmacist intern is a fit and proper person to be registered as a pharmacist; and

(iii) where the internship has been completed at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, a manufacturing pharmacy or a wholesale pharmacy, proof that the period of 400 hours practical training in a community pharmacy or institutional pharmacy has been completed in accordance with all the necessary requirements

Substitution of regulation 18 of Regulations

20. The following regulation is hereby substituted for regulation 18 of the Regulations:

Pre-registration evaluations

18. A person may be required to undertake a pre-registration evaluation, which may be conducted by the council, as a pre-requisite for registration as a pharmacist in terms of the Act: Provided that if such person fails such evaluation, the council may require—

(a) the person to be re-evaluated at a time and date as may be determined by the council; or

(b) the person's period of practical training to be extended by an additional period as the council may determine.".

21. Deletion of regulation 19 of Regulations

Regulation 19 of the Regulations is hereby deleted

Substitution of title of existing Chapter II of Regulations

22. The following title is hereby substituted for the existing title "**CHAPTER II Standards of education and training of pharmacists' assistants**" of the Regulations:

"**CHAPTER III**

Standards of education and training of pharmacist's assistants (basic) and pharmacist's assistants (post-basic)".

Substitution of regulation 20 of Regulations

23. The following regulation is hereby substituted for regulation 20 of the Regulations:

"**20.** Education and training programmes for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) shall be approved by the council."

Substitution of regulation 21 of Regulations

24. The following regulation is hereby substituted for regulation 21 of the Regulations:

"21. Only a provider that holds a certificate of approval for an education and training programme approved for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) may provide such education and training ".

Deletion of regulation 22 of Regulations

25. Regulation 22 of the Regulations is hereby deleted.

Deletion of regulation 23 of the Regulations

26. Regulation 23 of the Regulations is hereby deleted.

Substitution of regulation 24 of the Regulations

27. The following regulation is hereby substituted for regulation 24 of the Regulations:

24. Evaluation of prior learning. The council may, when it is deemed necessary by council, provide for an evaluation of prior learning by which a person shall be assessed prior to registration in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic): provided that the evaluation must be conducted in accordance with a procedure as determined by council from time to time and on payment of the evaluation fee as determined by council

Substitution of regulation 25 of Regulations

28. The following regulation is hereby substituted for regulation 25 of the Regulations:

"25. A learning programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), may be determined by a

provider provided that a minimum period of twelve months of in-service training must be completed.".

Amendment of regulation 27 of Regulations

29. Regulation 27 of the Regulations is hereby amended by the substitution for subregulation (3) of the following subregulation:

"(3) the tutor has been registered as such.".

Deletion of regulation 28 of Regulations

30. Regulation 28 of the Regulations is hereby deleted.

Substitution of regulation 30 of Regulations

31. The following regulation is hereby substituted for regulation 30 of the Regulations:

"**30. Supervision of pharmacy support personnel undergoing in-service training.** A pharmacist may at the same time, act as the tutor to no more than three pharmacist's assistants (learner basic) or pharmacist's assistants (learner post-basic), per category or a combination thereof, undergoing in-service training.".

Substitution of regulation 32 of Regulations

32. The following regulation is hereby substituted for regulation 32 of the Regulations:

"**32.** A provider approved to offer an education and training programme for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), must, upon

the successful assessment of the pharmacist's assistant in the said categories, submit to the registrar a notification of completion of such qualification, in a manner determined by the council."

Substitution of regulation 33 of Regulations

33. The following regulation is hereby substituted for regulation 33 of the Regulations:

"**33.** A person may be required to undertake an assessment or evaluation, which may be conducted by the council, as a prerequisite for registration in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic).".

Deletion of regulation 34 of the Regulations

34. Regulation 34 of the Regulations is hereby deleted.

Insertion of new Chapter IV in Regulations

35. The following new Chapter IV, together with the regulations made thereunder, is hereby inserted after regulation 34 of the Regulations:

"**CHAPTER IV**

Standards of education and training of pharmacy technicians

34A. Education and training programmes for purposes of registration as a pharmacy technician shall be approved by council."

34B. Only a provider that holds a certificate of approval for an education and training programme approved for purposes of registration as a pharmacy technician may provide such education and training'.

34C.(1) A person who has completed an education and training programme approved by the council for purposes of registration as a pharmacy technician must, prior to registration as a pharmacy technician, undertake a traineeship contemplated in this Chapter for a period or aggregate period of six months.

(2) The council may exempt a person referred to in subregulation (1), partially or in full, from the traineeship requirement contemplated in subregulation (1) on submission of documentary evidence to the satisfaction of the council that the person has undertaken work-based training as part of an education and training programme approved by the council for purposes of registration as a pharmacy technician.

34D.(1) The traineeship referred to in regulation 34D must be undertaken –

(a) in terms of a contract;

(b) under the direct supervision of a tutor;

(c) in a community pharmacy, institutional pharmacy, manufacturing pharmacy or wholesale pharmacy which provides a minimum number of services pertaining to the scope of practice of a pharmacy technician, as may be determined by the council in terms of the Act, and which is approved by the council in terms of the Act for purposes of such training.

(2) A traineeship undertaken in terms of subregulation (1)(c) in a manufacturing pharmacy or a wholesale pharmacy must include, as part of such traineeship, a period of not less than 200 hours

of practical training at a community or institutional pharmacy approved by council, in terms of the Act, for such training: Provided that—

(a) the tutor referred to in subregulation (1)(b) must –

(i) make the arrangements for the keeping of necessary records of such training; and

(ii) inform the council of the community or institutional pharmacy where the practical training will be undertaken;

(b) such periods of practical training must be undertaken at an approved community or institutional pharmacy and on the basis of periods each of which must be at least five consecutive days;

(c) there is a tutor at the pharmacy where practical training is undertaken who must keep records of such training;

(d) the responsibilities of all the parties regarding such practical training must be clearly documented and included in the terms of the traineeship contract; and

(e) under the direct personal supervision of a tutor registered by the council in terms of the Act.

34E. No person must commence a traineeship unless he or she is duly registered as a pharmacy technician (trainee) in terms of the Regulations Relating to the Registration of Persons and the Maintenance of Registers made in terms of the Act.

34F. No pharmacist or pharmacy may employ any person as an pharmacy technician (trainee) or in any other capacity which may imply or lead such person to believe that he or she is undertaking a traineeship, unless the requirements in regulations 34D and 34E have been complied with.

Cession of contract of traineeship

34G. (1) A contract contemplated in regulation 34D(1)*(a)* may be ceded in the event of –

(a) the death of a tutor, his or her conviction of a serious offence or suspension or removal of his or her name from the register of pharmacists during the contract;

(b) the discontinuation of practice of the tutor or the resignation of the tutor from the pharmacy approved for the traineeship;

(c) the closure of the pharmacy approved for the traineeship;

(d) mutual consent of the tutor and the pharmacy technician (trainee) for a reason, which is acceptable to the registrar; or

(e) any other reason the registrar may consider to be acceptable:

Provided that the period of traineeship undertaken by the pharmacy technician (trainee) under the original tutor must be recognised by the council for the purposes of traineeship and that the prospective tutor accepts the delegation of the rights, obligations and interests in terms of such a contract.

Approval of contract of cession

34H.(1) A pharmacy technician (trainee) intending to cede a contract to another tutor must, at least seven days before such cession occurs, submit to the registrar

(a) a duly completed application on a form as approved and provided by the council;

(b) a duly completed and signed contract of cession for the conducting of a traineeship approved and provided by the council;

(c) documentary evidence—

(i) of the approval by the council of the pharmacy where the traineeship of the pharmacy technician (trainee) will occur after cession of the contract;

(ii) of registration of the tutor under whose direct personal supervision such traineeship will take place;

(iii) in the form of an affidavit by the previous tutor, where possible, affirming that partial traineeship was successfully performed.

(2) The pharmacy technician (trainee) contemplated in subregulation (1) must pay the cession fee as may be determined by the council in terms of the Act.

34I. A pharmacist may act as a tutor to no more than one pharmacy technician (trainee) at a time, unless the pharmacy technician (trainee) already under training with such tutor has

completed his or her fifth month of traineeship, in which case the tutor may act as tutor to one other pharmacy technician (trainee) for the remainder of the traineeship period.

Assessment and completion of pharmacy technician traineeship

34J.(1) The tutor of a pharmacy technician (trainee) must submit to the registrar—

(*a*) assessment forms, obtainable from the council, on the progress of the pharmacy technician (trainee) during the period of traineeship; and

(*b*) an affidavit, at the end of the period of traineeship, affirming that—

(i) the training has been completed satisfactorily in accordance with council's requirements for traineeship; and

(ii) the pharmacy technician (trainee) is a fit and proper person to be registered as a pharmacy technician.

Pre-registration evaluations

34K. A person may be required to undertake a pre-registration evaluation, which may be conducted by the council, as a pre-requisite for registration as a pharmacy technician in terms of the Act: Provided that if a person requiring registration fails such evaluation, the council may require—

(a) such person to be re-evaluated at a time and date as may be determined by the council; or

(b) the person's period of traineeship to be extended by an additional period as the council may determine.

Substitution of title of existing Chapter III of the Regulations

36. The following title is hereby substituted for the existing title "**CHAPTER III Approval of tutors and premises for purposes of education and training**" of the Regulations:

"**CHAPTER V**

Registration of tutors and approval of premises for purpose of education and training

Registration of a tutor

Substitution of regulation 35 of Regulations

37. The following regulation is hereby substituted for regulation 35 of the Regulations:

"**35.**(1) A pharmacist who wishes to be registered as a tutor must submit to the registrar—

(a) a duly completed application for registration as a tutor of persons undergoing an internship, traineeship or in-service training, on a form obtainable from the council;

(b) in the case of a pharmacist who wishes to act as a tutor of a pharmacist intern, proof that he or she has been registered as a pharmacist for a period of at least three years, which period may include the performance of pharmaceutical community service; and

(c) proof of successful completion of continuing professional development in terms of the Act.

(2) A pharmacist contemplated in subregulation (1) must pay the necessary application fee as may be determined by the council in terms of the Act."

Substitution of existing title Chapter IV of Regulations

38. The following title is hereby substituted for the existing title "**CHAPTER IV**" of the Regulations:

"**CHAPTER VI**

Substitution of regulation 41 of Regulations

39. The following regulation is hereby substituted for regulation 41 of the Regulations:

"**41.**(1) Any provider intending to provide education and training for purposes of —

(a) registration as a pharmacist;

(b) registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician;

(c) registration of a speciality;

(d) continuing professional development

(e) supplementary training; or

a course determined by the council in terms of the Medicines Act,"

must apply to the council for approval.

(2) The application contemplated in subregulation (1) must be made on an application form obtainable from the council for such purpose.".

Substitution of regulation 42 of Regulations

40. The following regulation is hereby substituted for regulation 42 of the Regulations:

"**Conditions for approval**

42.(1) Any provider contemplated in regulation 41 must be approved, subject to the following conditions:

(a) providers of education and training for purposes of registration as a pharmacist may be approved for a maximum period of six years;

(b) providers of education and training for purposes of registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician may be approved for a maximum period of five years; and

(c) providers of continuing professional development courses, supplementary training and courses determined in terms of the Medicines Act, may be approved for a maximum period of three years.

(2) The pharmacy education and training programmes must be conducted in accordance with—

(a) good pharmacy education standards;

(b) good pharmacy practice;

(c) the code of conduct as published by council in rules in terms of the Act; and

(d) the provisions of other applicable legislation.".

Insertion of regulation 42A into Regulations

41. The following regulation is inserted after regulation 42 of the Regulations:

"**Appointment and duties of designated pharmacist**

42A. (1) A provider of pharmacy education and training must appoint and register a designated pharmacist for each approved institution.

(2) The designated pharmacist must be responsible to the council for complying with the provisions of the Act and other legislation relating to pharmacy education and training.

(3) The designated pharmacist must—

(a) ensure that the provider complies with all the requirements for approval including the payment of applicable fees;

(b) ensure that learners registered with the provider have complied with all the requirements for registration;

(c) furnish the registrar with information that the registrar may require from time to time;

(d) participate in the decision making process of the provider affecting pharmacy education and training;

(e) notify the council immediately upon receiving knowledge that his or her status as designated pharmacist has changed or will be changed;

(f) inform the registrar of any instruction or order from the institution with regard to the pharmacy education and training which could amount to a contravention of legislation applicable to pharmacy;

(g) take corrective measures in respect of deficiencies with regard to inspection reports emanating from monitoring and accreditation inspections; and

(h) ensure that there is compliance with good pharmacy education standards and practice and the code of conduct as published by the council in rules in terms of the Act.

Substitution of regulation 43 of Regulations

42. The following regulation is hereby substituted for regulation 43 of the Regulations:

"**Inspection of providers**

43. The council must inspect providers to measure compliance with the requirements determined by council for the provision of pharmacy education and training at intervals as determined by council from time to time."

Amendment of regulation 44 of Regulations

43. Regulation 44 of the Regulations is hereby amended by the addition of the following subregulation:

"(4) have the minimum of a Master's degree."

Substitution of regulation 48 of Regulations

44. The following regulation is hereby substituted for regulation 48 of the Regulations:

"**48.** The council must publish the names of providers that have been approved and registered to provide education and training in terms of the Act."

Deletion of Annexures

Annexure A. Annexure B and Annexure C are hereby deleted.

Short Title

45. These Regulations are called the Amendment Regulations relating to the pharmacy education and training, 2020.

DEPARTMENT OF HEALTH

NO. 659 **12 JUNE 2020**

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

REGULATIONS REGARDING FEES PAYABLE IN TERMS OF THE PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

The Minister of Health intends, in consultation with the Minister of Finance and the South African Health Products Regulatory Authority, in terms of Section 35(1)(xxxi) and **(xxxii)** read together with Section 35(4) of the Medicines and Related Substances, to make the Regulations in the Schedule.

Interested persons are invited to submit any substantiated comments on the proposed Regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 for the attention of the Director: Public Entities, Ms M Mushwana, mihloti.mushwana@health.gov.za within two months of this Notice

SCHEDULE

Definitions

1. In these Regulations, "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 1 of 1965).

Fees

2. The following fees shall be payable to the Chief Executive Officer or the Director General as the case may be:

Category A medicines

Human medicines, including Biologicals, for which an application for registration is submitted as contemplated in Section 15 of the Act.

(a) In respect of the submission of an application for registration of-

(i) New Chemical Entities, including highly technological products, which have

been processed by the abbreviated registration process [AMRP] (first strength, first dosage form): R111 000 per application;

(ii) Strengths and dosage forms other than those referred to in sub- paragraph (i): R 44 000 per application;

(iii) New Chemical Entities, new biotherapeutics other than vaccines (first strength, first dosage form): R208 400 per application;

(iv) Strengths and dosage forms other than those referred to in sub- paragraph (iii): R 82 000 per application

(v) Biological products e.g. vaccines (excluding new biotherapeutics): R177 000 per application;

(vi) Biological products e.g. biosimilars (excluding new biotherapeutics): R173 000 per application;

(vii) Strengths and dosage forms other than "those referred to in sub- paragraph (vi): R55 000 per application;

(viii) Generic products (pharmaceutical, analytical and bioavailability evaluated) including generic dental and radio-pharmaceutical products (first strength, first dosage form): R84 000 per application;

(ix) Strengths and dosage forms other than those referred to in sub- paragraph (vii): R27 000;

(x) Generic products with clinical data: R84 000;

(xi) Strengths and dosage forms other than those referred to in sub- paragraph (x): R27 000 per application;

(xii) Evaluation of additional submitted clinical data (pre-registration): R5 000; and

(xiii) An application in terms of Section 15C of the Act: R37 800.

(b) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act:

(i) In respect of registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act (in the case of medicines in minute-dose form; the fee encompasses different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid: R2 000 for each registration;

(ii) Evaluation of request for rescheduling of products: R16 000;

(iii) Evaluation of request to amend Professional Information and Patient Information Leaflets in respect of which data relating to safety must be evaluated (post registration): R15 600;

Evaluation of request to amend Professional Information and Patient Information Leaflets in respect of which clinical data relating to safety and efficacy must be evaluated (post registration): R15 600;

(iv) Evaluation of request to amend the Generic medicine package insert and Patient Information Leaflet where clinical data are not required (post registration): R2 600;

(v) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type II Level 1: R28 500;

(vi) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type II Level 2: R13 300;

(vii) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type II Level 3: R4 400;

(viii) Evaluation of request for minor technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type IA: R3 300;

(ix) Evaluation of request for minor technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type IB: R5 400;

(x) Evaluation of requests for approval of once-off deviations from registered requirements: R5 300;

(xi) Evaluation of requests for exemption from registered post-importation testing requirements per product: R5 300;

(xii) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): R5 000: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Authority in terms of Section 15(3); Provided further that the said fees payable during a particular calendar

year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).

(c) In respect of the testing of a human vaccine for purposes of batch release by the National Control Laboratory: R23 100 per batch.

Category C medicines

Veterinary medicines, including Biologicals, for which Authority has determined by resolution that they are registerable:

(d) In respect of the submission of an application for registration of-

(i) New Chemical Entities, including highly technological products, (first strength, first dosage form): R13 900 per application;

(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): R12 700 per application;

(iii) Generic products with clinical data: R13 900;

(iv) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii), (iii): R4 400;

(v) Screening fee on receipt of the application: R1 800;

(vi) Evaluation of additional submitted clinical data (pre-registration): R2 800.

(e) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3):

(i) In respect of the registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) (in the case of medicines in minute-dose forms; the fee encompasses different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid: R1 800 for each registration;

(ii) Evaluation of request for rescheduling of products: R6 200;

(iii) Evaluation of request to amend Professional Information in respect of which clinical data relating to safety and efficacy must be evaluated: R4 000;

(iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): R2 300. Provided that this provision shall come into effect one year after

the date on which the registration of the said medicine was approved by the Authority in terms of Section 15(3). Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).

Category D medicines (Human medicines)

Human medicines for which an application for registration has been submitted as contemplated in Section 15 of the Act,

(f) In respect of the submission of an application for registration of-

(i) Products submitted with clinical and or toxicological data (first strength, first dosage form): R14 300 per application;

(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i): R4 500 per application;

(iii) Products submitted with no clinical or toxicology data (first strength, first dosage form): R6 400 per application;

(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii): R2 100;

(v) Screening fee on receipt of an application: R1 800;

(vi) Evaluation of additional submitted clinical data (pre-registration):R2 900;

(vii) An application in terms of Section 15C of the Act: R34 700;

(g) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act:

(i) In respect of registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act and in respect of which an application fee has been paid: R1 800 for each registration;

(ii) Evaluation of request for rescheduling of products: R5 800;

(iii) Evaluation of request to amend Professional Information in respect of which clinical data relating to safety and efficacy must be evaluated (post- registration): R3 500;

(iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms

of Section 15(3): R1 800: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Authority in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).

Category D medicines (Veterinary medicine)

Veterinary medicines for which Authority has determined by resolution that they are registerable:

(h) In respect of the submission of an application for registration of -

(i) Products submitted with clinical and or toxicological data, (first strength, first dosage form): R3 900 per application;

(ii) Products submitted with no clinical or toxicology data (first strength, first dosage form): R2 800 per application;

(iii) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii): R1 600;

(iv) Screening fee on receipt of the application: R1 800;

(v) Evaluation of additional submitted clinical data (pre-registration): R1 500

(i) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3):

(i) In respect of the registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) and in respect of which an application fee has been paid: R1 800 for each registration;

(ii) Evaluation of request for rescheduling of products: R5 800;

(iii) Evaluation of request to amend Professional Information in respect of which clinical data relating to safety and efficacy must be evaluated: R3 500;

(iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): R1 300: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Authority in terms of Section 15(3): Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the

registration may be cancelled in terms of Section 16(4).

Fees for clinical trials

3. (a) In respect of the submission of an application for the authorisation of the use of an unregistered medicine for clinical trials:

i. Clinical trial application (Safety and efficacy): R32 400.00;

ii. Clinical trial application (Bioequivalence study): R30 400;

iii. Clinical trial application (Postgraduate study): R10 800;

iv. Any other clinical trial application: R5 000;

(b) In respect of clinical trials amendments:

v. Fees in respect of an application for technical amendments: R7 000.00 per amendment;

vi. Fees in respect of an application for administrative amendment: R4 100 per amendment.

Use of unregistered medicines (section 21 applications)

4. Any other application except for the purpose of performing a clinical trial: R350.

Fee for new licences

5. (a) An application for a new licence in terms of Section 22C (1)(b) of the Act:

i. Manufacture: R25 200;

ii. Distribute: R15 000 [Holder of certificate of registration (HCR)];

iii. Wholesale R15 000;

iv. Import: R15 000 (Holder of certificate of registration);

v. Export: R15 000 (Holder of certificate of registration).

(b) An application for the renewal of a licence in terms of Section 22D of the Act, the licensing of which has been approved by the Authority in terms of Section 22C(1)(b) of the Act:

i. Manufacture: R22 000;

ii. Distribute: R12 600 (Holder of certificate of registration);

iii Wholesale: R12 600;

iv Import: R9 200 (Holder of certificate of registration);

v Export: R9 200 (Holder of certificate of registration).

(c) Annually, in respect of the retention of a licence issued in terms of Section 22C(1)(b) of the Act: R4 200, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled;

(d) Licensing for any manufacturer, distributor, wholesale, import or export, the license of which has been approved by the Authority in terms of Section 22(1)(b) of the Act: R3 400;

(e) Application for the amendment to an existing licence to manufacture, distribute, wholesale, import or export: R5300.

Fees for inspections to assess the quality, safety and efficacy of medicines or scheduled substances

6. (a) Local manufacturing site: R1 600/h; (Travel time to be charged)

(b) International manufacturing sites: R1 600/h; (Travel time to be charged)

(c) Wholesale sites: R1 600/h,

(d) Distributor sites, Local: R1 600/h;

(e) Clinical trial site; Local: R1 600/h;

(f) International clinical trial site: R1 600/h;

(g) Local pharmacovigilance inspection: R1 600/h; and

(h) International pharmacovigilance inspection: R1 600/h.

(i) Desktop inspection to assess quality, safety and efficacy of medicines or scheduled substances: R2 100

Fees for permits and certificates

7. Fees for issuing of a permit or a certificate:

(a) Certificate [Certificate of a Pharmaceutical Product (WHO), Good Manufacturing Practice (GMP) Certificate, Certificate of Free Sale]: R1 400;

(b) Import permit (holder of certificate of registration): R950;

(c) Export permit (holder of certificate of registration): R925;

(d) Any other permit or certificate: R950;

(e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: R950.

Amendment of entries in register

8. Fee for all applications for amendments in terms of Section 15A, the name of the medicine approved by the Authority under Section 15(5), which shall be the proprietary name, the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine, the conditions of registration, the name of the applicant, the name and address of the manufacturer, packer, final product release control, final product release responsibility: R800 per application.

Transfer of certificates of registration

9. Fee for an application in terms of Section 158: R1 050 per application.

Appeal against the decision of the Authority

10. Fee for an application in terms of Section 24 (3): R50 000 per application.

Repeal of laws

11. Regulations published in Government Notice Government *Gazette* No 42474 Notice R 695 are hereby repealed.

Short title

12. These Regulations are called Regulations Regarding Fees Payable in terms of the provisions of the Medicines and Related Substances Act, 1965 (act no. 101 of 1965), 2020.

DR ZL MKHIZE, MP

MINISTER OF HEALTH

DATE: 8/4/2020

NATIONAL TREASURY

NO. 660 **12 JUNE 2020**

NOMINATION OF CANDIDATES FOR APPOINTMENT ON THE BOARD OF DIRECTORS OF THE LAND BANK IN TERMS OF THE LAND AND AGRICULTURAL DEVELOPMENT BANK ACT, 2002 (ACT No. 15 OF 2002)

In terms of Section 4(1) of the abovementioned Act, the Minister of Finance appoints directors to the Board of the Land Bank to manage the business of the Bank.

Members of the Board are appointed for a term of office determined by the Minister but not exceeding five years.

The Minister of Finance hereby invites persons and stakeholders to submit to him the names and curriculum vitae of persons with strong **Agricultural Sector Industrial Knowledge and Experience, Economics, Banking, Financial Management (Chartered Accountant), Financial Markets, Auditing, Legal, Information Technology, Digital, Human Resource Management, Development Finance and Governance** skills/experience to be considered for appointment on the Board of Directors of the Land Bank.

A written acceptance by the nominee, in a form of a letter, must accompany each nomination and each nominee must also certify that he or she is not disqualified to serve as a member of the Board as determined by Section 10 of the Act.

The Minister of Finance determines the remuneration allowances and other benefits of the Chairperson and other Board members.

Nominations should reach the address below not later than 26 June 2020.

If you have not received feedback from the National Treasury within 1 month of the closing date, please regard your application as unsuccessful.

Kindly address nominations to: **THE DIRECTOR-GENERAL: NATIONAL TREASURY, ATTENTION: DEPUTY DIRECTOR-GENERAL: ASSET AND LIABILITY MANAGEMENT, PRIVATE BAG X115, PRETORIA, 0001.**

Contact Person: Ms Rudzani Mandiwana
Tel. No. (012) 315-5543
Fax No. 086 543 2950
E-Mail: rudzani.mandiwana@treasury.gov.za

DEPARTMENT OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT

NO. 661 12 JUNE 2020

GEOMATICS PROFESSION ACT 19, 2013: INVITATION FOR WRITTEN NOMINATIONS TO BE CONSIDERED FOR APPOINTMENT TO THE SOUTH AFRICAN GEOMATICS COUNCIL.

I, Thoko Didiza, Minister of Department of Agriculture, Rural Development and Land Reform, acting in terms of Section 4(4) (a) read with 4(7) (a) of the Geomatics Profession Act, 2013 (Act No. 19 of 2013) ("the Act"), hereby invite nominations to be considered for appointment as members and alternate members of the South African Geomatics Council established in terms of Section 3(1) of the Act. This invitation includes the nomination of a person to represent the interest of the public in terms of Section 4(1) (d) of the Act.

Please note that in terms of Section 4(4) (b) of the Act, any person making a nomination is required to indicate which category and branch of registered persons is to be represented by such a nominee.

Please note further that in terms of section 4(5) of the Act:

"4(5) nominations must be supported by-

(a) the personal details of the nominee;
(b) particulars of the qualifications, experience in geomatics, or related matters or skills which may make the nominee suitable for appointment; and
(c) any other information that may be prescribed."

Written nominations must be forwarded within 14 days from the date of publication hereof, to:

Private Bag X 954
Pretoria
0001
Phone : (012) 326- 5703
Email address: or
Enquiries : N. Mazibuko or F. Lehabe

MS AT DIDIZA
MINISTER: AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT
DATE: 17- 03-2020

GENERAL NOTICES • ALGEMENE KENNISGEWINGS

ECONOMIC DEVELOPMENT DEPARTMENT

NOTICE 315 OF 2020

COMPETITION TRIBUNAL

NOTIFICATION OF COMPLAINT REFERRAL

The Competition Tribunal gives notice in terms of Section 51(3) & (4) of the Competition Act 89 of 1998 as amended, that it received the complaint referrals listed below. The complaint(s) alleges that the respondent(s) engaged in a prohibited practice in contravention of the Competition Act 89 of 1998.

Case No.	Complainant	Respondent	Date received	Sections of the Act
CR024May20	Competition Commission	Sicuro Safety CC	12/05/2020	8(1)(a)
CR025May20	Competition Commission	Hennox 638 CC t/a Hennox Supplies	12/05/2020	8(1)(a)
CR032May20	Competition Commission	Caprichem (Pty) Ltd	28/05/2020	8(1)(a)

The Chairperson
Competition Tribunal

ECONOMIC DEVELOPMENT DEPARTMENT

NOTICE 316 OF 2020

COMPETITION TRIBUNAL
NOTIFICATION OF DECISION TO APPROVE MERGER

The Competition Tribunal gives notice in terms of rules 34(b)(ii) and 35(5)(b)(ii) of the "Rules for the conduct of proceedings in the Competition Tribunal" as published in Government Gazette No. 22025 of 01 February 2001 that it approved the following mergers:

Case No.	Acquiring Firm	Target Firm	Date of Order	Decision
LM174Mar20	Mulilo Renewable Energy (Pty) Ltd	MRE Prieska and MRE DE AAR	13/05/2020	Approved
LM176Mar20	Mitsubishi Heavy Industries Ltd	Mitsubishi Hitachi Power Systems Ltd	13/05/2020	Approved
LM177Mar20	Adcock Ingram Healthcare (Pty) Ltd	Plush Professional Leather Care (Pty) Ltd	13/05/2020	Approved
LM002Apr20	Daimler Truck AG	Ukuvela Holdings (Pty) Ltd	27/05/2020	Approved
LM004Apr20	Gatsby Security SPV (Pty) Ltd	Cell C Ltd	27/05/2020	Approved Subject to Conditions
LM170Mar20	Nouryon Chemicals International B.V	CP Kelco OY	27/05/2020	Approved

The Chairperson
Competition Tribunal

INDEPENDENT COMMUNICATIONS AUTHORITY OF SOUTH AFRICA

NOTICE 317 OF 2020

DRAFT CODE FOR PERSONS WITH DISABILITIES REGULATIONS FOR FURTHER PUBLIC COMMENTS

1. The Independent Communications Authority of South Africa ("the Authority") hereby gives notice in terms of sections 4(3)(j) of the Independent Communications Authority of South Africa Act, 2000 (Act No. 13 of 2000) ("ICASA Act"), read with sections 4(1), 4(4) and 70 of the Electronic Communications Act, 2005 (Act No. 36 of 2005) "(ECA"), regarding its intention to prescribe a Code for Persons with Disabilities Regulations ("draft Regulations") contained in the schedule attached herewith.

2. A copy of the draft Regulations is also available on the Authority's website at http://www.icasa.org.za and in the Authority's Library at Block C, 350 Witch-Hazel Avenue, Eco Point Office Park, Eco Park, Centurion during the Authority's normal office hours.

3. Interested persons are invited to submit written representations on the draft Regulations within thirty (30) working days of the date of publication of this notice by either courier service, facsimile transmission or electronically (in Microsoft Word) for the attention of Ms Nditsheni Hangwani, Code for Persons with Disability Project Leader at: ICASA, Block B, 350 Witch-Hazel Avenue, Eco Point Office Park ,Eco Park, Centurion, or Fax:(012) 568 3418 or E-mail: nhangwani@icasa.org.za and CodeforPwDsCommittee@icasa.org.za .

4. All written representations submitted to the Authority pursuant to this notice will be made available for inspection by interested persons at the Authority's library and copies of such representations will be obtainable on payment of the prescribed fee.

5. When a person submits information to the Authority, such person may request that specific information be treated as confidential information in terms of section 4D of the Independent Communications Authority of South Africa Act, 2000 (Act No. 13 of 2000) ("ICASA Act"). The request for confidentiality must be accompanied by a written statement explaining why the specific information should be treated as confidential in terms of section 4D(4)(a) to (e) thereof.

6. The Authority may determine that such representations or any portion thereof is to be treated as confidential in terms of section 4D of the ICASA Act. Where the request for confidentiality is refused, the person who made the request will be granted an opportunity to withdraw such representations or portion(s) thereof.

7. Persons submitting written representations are further invited to indicate, as part of their submissions, whether they require an opportunity to make oral presentations.

DR KEABETSWE MODIMOENG
ACTING CHAIRPERSON
DATE 03/JUNE/2020

SCHEDULE

DRAFT REGULATIONS ON THE CODE FOR PERSONS WITH DISABILITIES

1. DEFINITIONS

In these Regulations, any word or expression to which a meaning has been assigned in the Act, has the meaning so assigned, unless the context indicates otherwise:

"**Act**" means the Electronic Communications Act, 2005 (Act No. 36 of 2005) as amended;

"**Accessibility**" means the ability by persons with Disabilities to equally access and benefit from broadcasting and electronic communications services;

"**Accessibility Services**" means a service such as Audio Description, Closed Captioning, Subtitles, or any other similar service;

"**Applicable Channels**" means all television channels broadcast by a television broadcasting licensee except a third-party channel(s) consisting predominantly of live programming content such as news, reality or sports;

"**Audio Description**" means oral commentary that gives a viewer who is blind or partially sighted a verbal description of what is happening on the television screen at any given moment. It is provided as an aid to the understanding and enjoyment of the programme. The technique uses a second sound track that gives a description of the scene and the on-screen action;

"**Closed Captioning**" means a process of converting the audio content of television broadcast or other production into text and displaying the text on a screen or monitor;

"**Disability**" For the purpose of these regulations, Disability refers to a long-term or recurring hearing and visual impairment;

"**National Relay System**" means phone services operated by interpreters that enable persons who are deaf or hard of hearing or who have a speech impairment, to

communicate by phone through an interpreter with a person who can hear in a manner that is "functionally equivalent" to the ability of an individual without a disability;

"**Performance Period**" the period of 126 hours in one week measured between 05h00 and 23h00 each day;

"**Photosensitive**" is when seizures are triggered by flashing lights or contrasting light and dark patterns;

"**Sign language**" means the South African Sign Language that uses a system of manual, facial, and other body movements as a means of communication;

"**Subtitles**" means a service by which both the audio dialogue and sound representations of a video programme, are made visible by the user via on-screen text that is synchronized with the audio content;

"**Universally Designed**" means the design of products, environments, programmes and services usable by all people, to the greatest extent possible, without the need for adaptation or specialised design;

"**Year 1**" means the twelve-month period commencing on the date on which these Regulations come into operation in accordance with regulation 14 of these Regulations.

2. PURPOSE AND SCOPE OF THE REGULATIONS

The purpose of these Regulations is to prescribe a Code for Persons with Disabilities, to be adhered to by Electronic Communications Service ("ECS") licensees and broadcasting service licensees, aimed at ensuring that persons with Disabilities have access to services.

3. BASIC STANDARDS FOR BROADCASTING SERVICE LICENSEES

Accessibility Services

(1) A television broadcasting service licensee must implement the following Accessibility Services on Applicable Channels: -

(a) Audio Description;
(b) Sign Language;

(c) Subtitles; and

(d) Closed Captioning.

Audio Description

(2) The objective of Audio Description is to aid the understanding and enjoyment of a television programme.

(3) A broadcasting service licensee must maintain quality access to Audio Description, which is essential for ensuring that audiences using broadcasting services benefit from them.

Sign Language

(4) A television broadcasting service licensee must:

(a) ensure that the viewer can see not only the hands but also, where applicable, the facial expressions of the interpreter;

(b) monitor the effectiveness of the service through annual consultations with organisations representing hearing impaired persons; and

(c) ensure that sign language interpreters employed have a recognised sign language qualification from an accredited institution.

Subtitles

(5) A television broadcasting service licensee which provides Subtitles must:

(a) provide Subtitles as near synchronous to speech as is practicable;

(b) reflect the spoken word with the same meaning;

(c) construct Subtitles which contain easily read sentences, and commonly used sentences in a tidy and sensible format; and

(d) give proper contrast between foreground and background colours.

4. GENERAL REQUIREMENTS FOR COMMUNICATION AND INFORMATION PROVISION TO PERSONS WITH DISABILITIES FOR BROADCASTING SERVICE LICENSEES

Provision for Breaking News

CONTINUES ON PAGE 130 - PART 2

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PART 2 OF 2

(1) A television broadcasting service licensee must provide for a news text strapline, in case of breaking news across channels.

Improving accessibility

(2) A television broadcasting service licensee must ensure that its services are made available and are accessible to persons with Disabilities.

(3) A television broadcasting service licensee must ensure that there is access to programme support including fact sheets and electronic programme guides (EPGs) on its website or its applications.

(4) A television broadcasting service licensee may make broadcasting services more accessible to persons with Disabilities by doing the following: -

(a) providing a range of formats on a television broadcaster's website (such as electronic versions and audio clips);
(b) incorporation of Accessibility Services into advertisements, economic indicators, weather details, telephone numbers and addresses or details of goods and services shown on screen; or
(c) making use of non-scheduled services such as access via personal video digital recorders (PVRs) and video on demand (VOD).

Warning to photosensitive viewers

(5) A television broadcasting service licensee must take special care when providing content that may disturb photosensitive audiences/viewers and issue warnings on the television screen prior to broadcasting for persons with photosensitive epilepsy.

(6) A television broadcasting service licensee must implement the minimum level applicable to Accessibility Service relevant to its broadcasting service licence category, as follows:

Subtitles:

(a) A broadcasting service licensee that provides Subtitles must implement the following minimum percentages of total Subtitles, measured across its

broadcasting service on Applicable Channels:

Minimum Subtitling requirements				
	Public	**Commercial free to air**	**Subscription**	**Community**
Year 1	10%	5%	2.5%	2%
Year 2	20%	5%	2.5%	2%
Year 3 onwards	30%	10%	5%	4%

Audio Description:

(b) A television broadcasting service licensee which provides Audio Description must implement the following minimum percentages of total Audio Description, measured across its broadcasting service on Applicable Channels:

Minimum Audio Description requirements				
	Public	**Commercial free to air**	**Subscription**	**Community**
Year 1	2%	1%	1%	0.4%
Year 2	4%	2 %	1%	0.8%
Year 3 onwards	6%	3%	1.5%	1.25%

Closed Captioning:

(c) A television broadcasting service licensee which provides Closed Captioning must implement the following minimum percentages of total Closed Captioning, measured across its broadcasting service on Applicable Channels:

Minimum Closed Captioning requirements				
	Public	**Commercial free to air**	**Subscription**	**Community**

Year 1	5%	2%	2%	1%
Year 2	5%	3 %	3%	1%
Year 3 onwards	10%	5%	5%	2%

5. BASIC STANDARDS FOR ELECTRONIC COMMUNICATIONS SERVICE LICENSEES

Universally Designed Products and Services:

(1) An Electronic Communications Service licensee must ensure that all electronic communications devices ready for purchase are Universally Designed to cater for the needs of persons with Disabilities.

Hearing Aid Compatibility Requirements for Fixed Line Handsets:

(2) An Electronic Communications Service licensee must ensure that all its fixed line telephones being offered to the public have hearing aid compatibility. Some of the features may include the following:

(a) a standard rental telephone handset which includes one-touch dial memory, a lightweight handset and a built-in hearing aid coupler;
(b) a telephone which amplifies the incoming caller's voice to suit the listener;
(c) a telephone which amplifies the speaker's voice, allowing the speaker to adjust the speech level to suit the listener;
(d) a hands-free telephone for a person who cannot hold a telephone handset;
(e) an ancillary telecommunications product which has adjustable volume, tone and pitch controls to assist the user to hear the telephone ringing;
(f) an ancillary telecommunications product which allows the connection of a second piece of equipment (e.g. a visual signal alert) in parallel with the existing telephone;
(g) an ancillary telecommunications product in which the telephone handset is cradled, providing hands-free operation; or
(h) a telephone adapting device which allows a person with cochlear implant to have access to the standard telephone service.

Visual Aid Compatibility Requirements for Mobile Handsets:

(3) An Electronic Communications Service licensee must ensure that all its mobile handsets being offered to the public have visual aid compatibility. Some of the features may include the following:

(a) **Customized Displays -** An Electronic Communications Service licensee must make provision for wireless device screens with better contrast, illumination, larger font size and magnifying functionalities;

(b) **Alternate formats** – An Electronic Communications Service licensee must make provision for product information and billing in alternate formats (Braille, large print, electronic (plain text or HTML, audio format etc.) upon request, and ensure that this information is easily accessible on the operators' website;

(c) **Braille** – An Electronic Communications Service licensee must make provision for phones that have built-in, or that make use of applications that have the capability of connecting wirelessly. When set up, it must support navigation and text input from a Braille keyboard;

(d) **Screen Reader** – An Electronic Communications Service licensee must make provision for a screen access application that provides individuals, who are blind or visually impaired, with the ability to read the text that is displayed on the computer screen with a speech synthesizer;

(e) **Voice Recognition** – Electronic Communications Service licensees must provide options for consumers to interact with their phone using their voice, or voice recognition;

(f) **Automatic Responses** - Electronic Communications Service licensees must provide a program on wireless devices to answer automatically or redial certain calls or messages; Hands-free or One-Touch - Electronic Communications Service licensees must provide a hands-free device with a speakerphone or assign certain functions to one button for dialling or other pre-programmed functions.

6. NATIONAL RELAY SYSTEM ("NRS")

(1) An Electronic Communications Service licensee must provide for a NRS which translates voice to text and vice-versa, on calls made by persons who are deaf or have a hearing or speech impairment.

(2) The NRS must offer the following relay services:

(a) Type and read;
(b) Speak and listen;
(c) SMS or text based services;
(d) Video; and
(e) Captioned telephony.

(3) An Electronic Communications Service licensee must comply with the NRS specifications, applicable to video, as contained in Annexure A of these Regulations.

(4) The NRS specification, applicable to video, must be implemented as follows:

Timeline	**Operating hours**
Year 1	09h00 -18h00
Year 2	06h00 - 22h00
Year 3 onwards	24 hours

7. GENERAL REQUIREMENTS FOR COMMUNICATION AND INFORMATION PROVISION TO PERSONS WITH DISABILITIES FOR INDIVIDUAL ELECTRONIC COMMUNICATION SERVICE ("I-ECS") LICENSEES

(1) An I-ECS licensee must provide free directory services to the hearing and sight impaired persons upon request.

(2) **Emergency services:** An I-ECS licensee must provide a special number for emergency services by including functionalities for persons with Disabilities.

(3) **Priority fault repairs:** An I-ECS licensees must prioritise an urgent need to repair a handset for persons with Disabilities.

(4) **Customer Service Staff:** An I-ECS licensee must ensure that there are trained employees who can provide customer service and communicate with persons with Disabilities in all its stores.

(5) **Demonstration of equipment:** An I-ECS licensee must ensure that it provides a demonstration in respect of the use of the equipment to persons with Disabilities who visit a broadcasting service or I-ECS licensee's store before the person purchases, where reasonably possible.

(6) **Access to information:**

(a) Television and broadcasting service and I-ECS licensees must:

(i) ensure that, where practicable, they provide upon request printed material outlining accessible products for persons with Disabilities in simple and reader friendly languages in all their stores;
(ii) provide brochures, videos and other information to organisations that work with deaf persons on a regular basis to ensure the information provided is displayed on information stands and targeted to deaf persons;
(iii) make available advertisements and promotions for products and services specifically designed for persons with Disabilities in accessible formats to relevant organisations of persons with Disabilities in every province upon request;
(iv) make provision for specific needs offers categorised according to disabilities, including hearing, sight, and dexterity disabilities which must be easily accessible on the operators' website.

8. PROMOTION OF AWARENESS AND COMPLIANCE BY A BROADCASTING SERVICE LICENSEE

(1) A television broadcasting service licensee must prepare a three-year accessibility plan setting out measures for that licensee to promote accessibility for persons with Disabilities to its broadcasting service ("accessibility plan").

(2) The accessibility plan, in terms of sub regulation (1), must set out the licensee's objectives and proposed measures to be implemented by the licensee in the following three years in relation to accessibility services for:

(a) blind and visually impaired persons; and
(b) deaf and hearing-impaired persons.

(3) A television broadcasting service licensee must submit its accessibility plan, in terms of sub regulation (1), to the Authority for approval six months after commencement of regulations and at three yearly intervals thereafter.

(4) The Authority may request the television broadcasting service licensee to make amendments to the accessibility plan, submitted in terms of sub regulation (3), should it deem it to not be sufficient.

(5) The measures set out in the accessibility plan, prepared in terms of sub regulation (1), are binding commitments with which the television broadcasting service licensee must comply.

(6) A television broadcasting service licensee is required to submit annual reports to the Authority on their accessibility initiatives and the extent to which they have implemented the measures in their accessibility plan.

(7) The reports, submitted in terms of sub section (6), must indicate the extent to which the broadcasting service licensee has implemented the measures in the preceding financial year, the extent to which it has implement the measures and the reasons for its non or partial compliance.

(8) A broadcasting service licensee's failure to implement the measures in its accessibility plan without, except for where noncompliance is as result of impossibility of performance, will constitute non-compliance with the Code.

9. COMPLIANCE REPORTING

A television broadcasting service and I-ECS licensees must submit annual reports to the Authority, sixty (60) days after the end of the licensee 's financial year, on the nature and extent of the licensee's compliance with these Regulations.

10. CONTRAVENTIONS AND PENALTIES

A licensee that fails to comply with these Regulations, except for regulation 4 (4), will be subject to a fine not exceeding R5 000 000, 00 (five million rand) or 10% of the licensee's annual turnover for everyday or part thereof during which the contravention continued.

11. REPEALED REGULATIONS

The Code on Persons with Disabilities Regulations published in Government Gazette No. 30441 of 2007 is hereby repealed.

12. TRASITIONAL ARRANGEMENTS

An existing terrestrial television broadcasting service licensee which is migrating from analogue to digital terrestrial transmission will be required to begin complying with these Regulations with effect from the date of the final switch-off of analogue signals gazetted by the Minister.

13. SHORT TITLE AND COMMENCEMENT

These Regulations are called the Code for Persons with Disabilities Regulations, 2020 and shall come into effect eighteen (18) months after publication in the Government Gazette.

Annexure A

National Relay System Specifications Applicable to Video

1. Technical Provision

1.1. Technical Provision

A Video Relay Service (VRS) allows hearing impaired and deaf people to use video technology to communicate in a manner similar to a traditional telephone call via a South African Sign Language interpreter (SASLi.)

VRS is a video interpreting service providing instant communication, on demand, between a South African Sign Language (SASL) user and a third party whereby the parties are in different locations (not co-located). For example, SASL user with webcam, videophone, mobile or tablet etc makes a video call and then signs to SASL Interpreter. A SASLi then speaks (via phone) to the hearing person. The hearing person replies (speaks) to the SASLi and the Sign Language Interpreter then translates (signs) the response to the deaf person (who can see the interpreter on their computer, TV or video screen). This process takes place simultaneously.

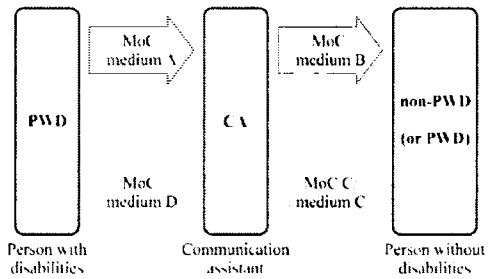

Figure 1

Notes to Figure 1: – MoC: Mode of communication.
CA: Communication Assistant - A person working in a relay service with media conversation, as a human intermediary, including sign language interpreters for video relay service
PWD: Persons With Disabilities

1.5. Service Allocation

The end user must be able to access all VRS services.

1.6. Emergency Calls

Emergency calls must be prioritised. Location and mapping detail are also required where available (access to subscriber information). Real time text will be required in order to provide an alternative method of communication.

The key functional requirements for placing emergency calls are[1]:

a) accurate and fast routing of the relay to the appropriate emergency call centre: the call centre that the relay service connects to must be the call centre that would have been reached if a non-PWD had made the emergency call in a similar situation. Furthermore, the emergency call centre must receive the call through their normal incoming emergency call phone lines, the same way that a voice emergency call is received from a non-PWD. If CA availability is limited, emergency calls should be prioritized (i.e., emergency callers can jump the queue of calls waiting for the next available CA to take a call);

b) accurate conveyance of all supporting information: information on the phone line and the location as it pertains to the PWD, not to the relay centre must be delivered. To the extent that an emergency call centre has access to such information from a non-PWD caller, the same information must be conveyed about a PWD who connects to the emergency services through a relay service

[1] Rec. ITU-T F.930 (03/2018)

conversation at low bit rates (based on the use of dated equipment or network access at the user end), the following basic minimum performance goals must apply:

- 25-30 frames per second at CIF resolution and a max. 0.4s delay, accepting occasional blur less than that corresponding to QCIF during medium motion.
- Sound synchronism better than 100 ms.
- End-to-end delay (latency) must be below 0.4 s. must

• Broadband Access - Broadband access requirements will be defined by the service provider based on the end user device, (mobile, pc, tablet) the type (fixed or mobile) and capability of network infrastructure (e.g. DSL, Ethernet, 3G, 4G) used as well as the quality of service offered.

1.9. Service Initiation and Operation

All VRS systems must be simple to operate from the Call centre application to the End user application. It must be easy to load with adequate loading instructions and simple to configure. It must be self-loading with minimum user intervention.

1.10. Call Handover

During peak busy hours priority calls (e.g. emergency calls) may need to be transferable between providers, provision must be made in this regard.

1.11. Call Back Provision

Caller's numbers or ID's must be temporarily stored to enable call back provision where required. There must be clear policies and procedures in place as to when and how this will be done, reflecting the needs of Data Protection. The user may not be charged extra for this service, neither connection fees or for additional minutes accrued as a result of re-establishing the call. The caller information must be removed within a designated timeframe or at a pre-

Privacy, confidentiality and security shall be maintained to achieve functional equivalency. Privacy, confidentiality and security considerations extend both to the technologies used by relay services and the human CAs.

Relay services shall be able to provide encrypted calls if the mainstream telephone services of the country in which the relay service is located provides encrypted calls. More generally, requirements for confidentiality and call security should mirror those of the mainstream telecommunications services of the country in question.

1.14. Standards

Services provision must conform to the relevant International Telecommunication Union communication protocols and specifications where available. Conformance to standards must be confirmed by the service providers in an auditable manner.

1.16 User Applications

User Applications consists of mobile applications for smartphones and a web-based interface for desktop computers. In addition to telephone numbers, the ability to use web-based links for direct service opportunities must be included in the VRS. This will provide a tremendous amount of accessibility for the end-user.

1.17 Interpreting Services

The core of the NRS are the interpreters. The service provider must set up a call centre and provide a sign language interpreter to enable the service.

Independent Communications Authority of South Africa

EXPLANATORY MEMORANDUM ON THE DRAFT CODE FOR PERSONS WITH DISABILITIES REGULATIONS

1. INTRODUCTION

1.1 In 2011, the Independent Communications Authority of South Africa ("Authority"), through the Committee for the Code for Persons with Disabilities began the process of reviewing the Regulations on the Code for Persons with Disabilities, 2007.

1.2 On 28 March 2014, the Authority published the first draft regulations on the Code for Persons with Disabilities for public comments in Government Gazette No.37486. Subsequent to receiving the written representations in response to the first draft, the Authority published a second draft regulation for another round for public comments on 14 November 2014 in Government Gazette No 38211. The Authority then published the third draft on 20 November 2017 in Government Gazette No. 41265.

1.3 The Authority held a consultative workshop on 06 and 07 of June 2019 with relevant stakeholders.

3. AMENDMENTS TO THE THIRD DRAFT REGULATIONS

3.1 AD DEFINITIONS:

National Relay System: It is important that persons that are deaf or hard of hearing or who have a speech impairment, can communicate by phone through the services of an interpreter. The National Relay System is thus inserted into the draft regulations to cater for a service that provides communication for persons with Disabilities as defined in the draft regulations.

3.2 AD BASIC STANDARDS FOR BROADCASTING SERVICE LICENSEES:

In the previous draft regulations, "**sign language**" was defined but not incorporated in the body of the regulations. This has now been addressed in the draft regulations.

3.3 AD GENERAL REQUIREMENTS FOR COMMUNICATION AND INFORMATION PROVISION TO PERSONS WITH DISABILITIES FOR BROADCASTING SERVICE LICENSEES:

3.3.1 The following requirements were included in the draft regulations:

(a) Provision for Breaking News; and
(b) Improving accessibility.

3.3.2 **Provision for breaking news:** every person is entitled to breaking news, including persons with a disability. The previous drafts failed to cater for persons with Disabilities in this regard.

3.3.3 **Improving accessibility:** persons with Disabilities must have access to information and entertainment, thus the insertion of this requirement in the draft regulation ensures inclusion for persons with Disabilities.

Authority's view that the contravention of the Regulations must be viewed in a serious light as the contravention thereof deprives persons with Disabilities with access to information and their rights to dignity.

PARLIAMENT OF THE REPUBLIC OF SOUTH AFRICA

NOTICE 318 OF 2020

MR GHALEB CACHALIA, MP

NOTICE OF INTENTION TO INTRODUCE A PRIVATE MEMBER'S BILL AND INVITATION FOR COMMENT ON THE DRAFT, NAMELY THE PUBLIC FINANCE MANAGEMENT AMENDMENT BILL, 2020

Mr Ghaleb Cachalia, MP, acting in accordance with section 73(2) of the Constitution of the Republic of South Africa, 1996, intends to introduce the Public Finance Management Amendment Bill, 2020 ("draft Bill"), in Parliament. An explanatory summary of the Bill is hereby published in accordance with Rule 276(1)*(c)* of the Rules of the National Assembly (9th Edition).

The Public Finance Management Act, 1999 (Act No. 1 of 1999) ("the Act") regulates financial management in the national government and provincial government and ensures that all revenue, expenditure, assets and liabilities of those governments are managed efficiently and effectively. Furthermore, the Act provides for the responsibilities of persons entrusted with financial management in those governments.

Section 65 of the Act provides that the executive authority responsible for a department or public entity must table annual reports, financial statements, and the audit report on those statements in the National Assembly, or in a provincial legislature as the case may be. The annual reports, financial statements and the audit reports on such statements, must be tabled within one month after the accounting officer for the department or the accounting authority for the public entity has received the audit report.

Section 65 of the Act further provides that if the executive authority fails to table these reports and statements in the relevant legislature within six months after the end of the financial year to which those statements relate, the executive authority must table a written explanation in the legislature setting out the reasons why they were not tabled. However, the Act does not provide for additional measures in instances where such reports and statements are not tabled, and the department or public entity is not required to table such reports and statements within a specified time-period after a written explanation has been tabled.

The draft Bill therefore seeks to provide for additional measures in instances where the executive authority fails to table an annual report and financial statements of a department or a public entity, and the audit report on those statements, in the National Assembly or the relevant legislature. The

Bill proposes that the annual report, financial statements, and the audit report on such statements referred in section 65 be tabled within 60 days after a written explanation has been tabled.

Interested parties and institutions are invited to submit written representations on the proposed content of the draft Bill to the Speaker of the National Assembly within 30 days of the publication of this notice. Representations can be delivered to the Speaker, New Assembly Building, Parliament Street, Cape Town; mailed to Speaker, P O Box 15 Cape Town 8000, or emailed to speaker@parliament.gov.za and copied to lurwinj@da.org.za

Copies of the Bill may, after introduction, be obtained from:

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