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11 September 2020

Attention: Ms Mihloti Mushwana
Director: Public Entities Governance
By Email: regulationcomments@health.gov.za

Dear Ms Mushwana,

Re: Comments on the Draft Regulations to the Pharmacy Act, 1974 (ACT NO. 53 of 1974) as Published on 12 June 2020.

This input is provided in response to the request issued in the following Government Notices, which included draft Regulations to be issued in terms of the Pharmacy Act (Act 53 of 1974):

1. Pharmacy Act: Regulations: Registration of Persons and Maintenance of Registers: Amendment. Government Notice No. 656, Government Gazette No. 43418, 12 June 2020 (https://www.gov.za/sites/default/files/gcis_document/202006/43418gon656s.pdf)
2. Pharmacy Act: Regulations: Practice of Pharmacy: Amendment. Government Notice No. 657, Government Gazette No. 43418, 12 June 2020 (https://www.gov.za/sites/default/files/gcis_document/202006/43418gon657s.pdf)
3. Pharmacy Act: Regulations: Pharmacy Education and Training: Amendment. Government Notice No. 658, Government Gazette No. 43418, 12 June 2020 (https://www.gov.za/sites/default/files/gcis_document/202006/43418gon658s.pdf).

As requested, the specific input is provided as Tables, below. However, some background material and principles are covered first. A very specific legal concern is raised, which needs to be resolved before considering the substantive input provided on the draft Regulations.

Background

This input is submitted by the Pharmaceutical Society of South Africa (PSSA), a voluntary professional association representing pharmacists, pharmacy support personnel and pharmacy students. PSSA members practise in the community, institutional (hospital), industrial and academic sectors, and in both the public and private sectors.

This input is based on a wide-ranging series of comments communicated to the PSSA head office from its sectoral organisations, branches and individual members. In addition, input was provided by the Independent Community Pharmacists Association (ICPA). Many of the inputs received expressed concerns about the apparent diminution of the acts specially pertaining to the profession and the narrowing of the gap between pharmacists and pharmacy support personnel. The inputs pointed to the increasing role of large commercial entities in many areas of practice, including community and institutional pharmacy, and the pressures exerted on employees in both the public and private sectors. Concern was also expressed about the potential over-production of pharmacy graduates, the shortage of internship and community service posts, and the spectre of pharmacist unemployment. It is in the context of these pressures and changes that many of the concerns raised need to be understood.

Principles

This input is, nonetheless, informed by the principles upheld by the PSSA, its sectors, branches and members. The following statements of principle are pertinent to the issues raised in the proposed Regulations:

1. The PSSA is committed to the ideal of universal health coverage (UHC), which must include a comprehensive pharmaceutical service, capable of delivering equitable access to safe and effective medicines and other health technologies, and the necessary advice to ensure that the desired clinical outcomes from the use of such medicines and health technologies are attained. In South Africa, the delivery of UHC is expected to occur through the introduction of National Health Insurance (NHI). The proposed Regulations must therefore take into account the expected changes to the delivery of healthcare services that will accompany the implementation of NHI, and not only the fragmented health system that prevails at present, and which is a direct consequence of previous discriminatory policies. In addition, this legislative effort must be seen to contribute to the progressive attainment of the rights enshrined in section 27 of the Constitution.
2. The PSSA is supportive of the concept of task shifting, applied broadly across the health system. In particular, the PSSA supports the development of mid-level worker options for the delivery of cost-effective health services, including the development of a fit-for-purpose pharmacy support personnel cadre. The PSSA has embraced membership by pharmacist's assistants, and produces a regular journal catering specifically for the needs of pharmacy support personnel.
3. The PSSA supports the creation of a dual-track education and training process for pharmacy technicians, which takes into account the financial barriers to accessing tertiary institutions and provides for an alternative pathway via the Occupational Qualifications Framework.
4. The PSSA recognises that the development of clear and explicit scopes of practice for all pharmacy personnel is absolutely key to ensuring the delivery of an effective pharmaceutical service in all sectors, and to protecting the safety and health of patients and caregivers. Although pragmatic decisions are needed in a time of resource constraints, the primacy of each patient's right to safe healthcare must always be respected.
5. The same standards should also apply equally in both the public and private sectors, in accordance with the injunction in section 52A of the Pharmacy Act, which reads "This Act binds the State". We would argue that a non-discriminatory regulatory regime is a constitutional imperative, which cannot be breached, even when attempting progressive realisation of the right of access to healthcare services in the context of resource constraints.

A legal concern

South African law is based on a hierarchical relationship, first of the Constitution in relation to all other laws, but secondly on the appropriate relationship between primary, secondary and tertiary legislation. Based on this principle, secondary legislation, in the form of Regulations issued by a Minister, cannot countermand or contradict the provisions of primary legislation, in the form of Acts of Parliament.

In this regard, the proposed Regulations to be issued by the Minister of Health in terms of the Pharmacy Act must be read together with all other relevant legislation, and in particular primary legislation. Section 22A of the Medicines and Related Substances Act (Act 101 of 1965) is particularly important as it governs the control over medicines and scheduled substances. Sub-section 22A(4) reads (with emphasis added):

"(4) Any Schedule 1 substance shall not be sold—
(a) by any person other than—
(i) a pharmacist, or a pharmacist intern **or pharmacist's assistant acting under the personal supervision of a pharmacist**;
(ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
(iii) a medical practitioner or dentist, who may—
(aa) prescribe such substance;
(bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
(iv) a veterinarian who may prescribe, compound or dispense such substance;
(v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may—
(aa) prescribe only the Scheduled substances identified in the Schedule for that purpose;
(bb) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C (1) (a);"

Likewise, sub-section 22A(5) reads (with emphasis added):
(5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than—
(a) a pharmacist, pharmacist intern or a **pharmacist's assistant acting under the personal supervision of a pharmacist**, who may sell only Schedule 2 substances without a prescription;
(b) a pharmacist or a pharmacist intern or **pharmacist's assistant acting under the personal supervision of a pharmacist**, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;
(c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
(d) a medical practitioner or dentist, who may—
(i) prescribe such substance;
(ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
(e) a veterinarian who may prescribe, compound or dispense such substance;
(f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may—
(i) prescribe only the Scheduled substances identified in the Schedule for that purpose;
(ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a)."

Lastly, sub-section 22A(14) reads (emphasis added):
(14) Notwithstanding anything to the contrary contained in this section—
(a) a **pharmacist's assistant** shall not handle any specified Schedule 5 or Schedule 6 substance except as contemplated in subsection (5) (a) and (b);".
While the PSSA acknowledges the considerable difficulty that has been experienced in amending primary legislation such as the Medicines Act, it respectfully asks whether a Regulation issued in terms of the Pharmacy Act can contradict another Act of Parliament without being considered to fail the test of legality. It is not clear that parsing "personal supervision" into two categories (direct and indirect) changes the ordinary meaning of the primary legislation, or the manifest intent of the legislator.

This issue has specific relevance for the delictual liability which might fall on a pharmacist who indirectly supervises a pharmacist's assistant (regardless of category), or who permits a pharmacist's

assistant to “handle” a medicine containing a specified Schedule 5 of Schedule 6 substances, in direct contravention of the Act. It could be argued that such a pharmacist would forfeit any protection under an indemnity insurance policy, for instance. To allow someone to perform a task for which s/he is not adequately trained, or legally entitled to perform, would be considered to constitute negligence. In this regard, the pharmacist would be held to a higher standard than the reasonable person, on account of her/his expertise and training.

Notwithstanding the fact that indirect supervision of pharmacist’s assistants (post-basic) has been in effect since 2003, the PSSA requests that urgent legal advice on this question be obtained from the State Law Advisers, before the proposed Regulations are finalised. Amendment of the Medicines Act may be needed, in addition to the legal manoeuvre of declaring pharmacy technicians a category of pharmacist’s assistant.

Substantive input

The substantive input from the PSSA is provided as three tables attached to this letter, for each of the draft Regulations published for comment.

Conclusion

Pharmacy is a science based and patient focused profession that deals in matters that can mean the difference between life or death, health or sickness, pain and suffering or its amelioration. Double standards in service delivery, in any form, should be strongly and totally resisted. ALL patients are equal and entitled to an equal quality of pharmaceutical service.

It should and can only be a registered Pharmacist that carries the ultimate responsibility and authority for every action within the scope of practice of a Pharmacist **– none other**. Responsibilities can always be delegated but never abdicated

There is one standard for GMP, relaxation for any reason in any practice reduces the standard of the whole profession. One exception, anywhere, will lead to increasing relaxation or accommodation throughout the profession until the cancer eventually diminishes the total profession and service delivered. An imposed relaxation of standards in one area will impact the quality of service at patient level throughout all areas

The existing core weakness that these regulations appear to attempt to overcome, must be addressed without sacrificing the standards of the profession or the control of pharmaceutical services by undermining the authority and responsibility of the Pharmacist.

Those elements of the proposals that appear to weaken universal pharmaceutical standards, or control of the profession without the direct involvement of a Pharmacist, require to be formally and strongly resisted. Failure to understand this must logically result in the replacement of Pharmacists and a spiralling loss of this important component of health delivery for our people.

Yours Sincerely

Joggie Hattingh
President

Ivan Kotze
Executive Director

TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS RELATING TO THE REGISTRATION OF PERSONS AND THE MAINTENANCE OF REGISTERS, MADE IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974) (GoN 656)

Comment no.	**Regulation, subregulation or paragraph**			**Comments and Rationale**	**Proposed Revised Text** **Bold underline** – additions **[square brackets bold]** – deletions
	Reg	Sub reg	Par		
1.				Definitions: Omission of pharmacy technician (learner) under the definition of “tutor”	"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) **or pharmacy technician (learner)**;
2.	2	(a)		Although consistently handled throughout, the reasoning behind deleting the term “certificate of qualification” is not adequately explained in the explanatory notes that precede the Draft Regulation.	Nil – clarification needed.
3.	2	(c)		Is the intention to preserve THREE categories of pharmacist’s assistants in perpetuity (basic, post-basic and technician)? If so, is the fine distinction between the PAPB and PT necessary in the long-term, or can the legacy category of PAPB be removed in time?	Nil, unless it is decided that the categories need changing in time.
4.	2	(e)	(d)	Is the formal approval and registration of a provider of continuing professional development necessary or even desirable, given the commitment of the SAPC to a CPD cycle that does not depend on points earned from such providers? While some measure of control over such providers might be considered appropriate, might it not create a market for high-cost CPD activities and detract from the self-directed, reflection-informed cyclical approach that has been created by the current guidelines?	Consider deletion of (d) and renumbering of sub-sections
5.	2	(e)		The final line “a course determined by the Council in terms of the Medicines Act” needs to be numbered. Although there is some logic to the vague wording, would it not be better to explicitly state that	Add sub-section (f) (unless renumbered as per comment 3)

				these are courses in compounding and/or dispensing, as provided for in section 22C(1)(a) of the Medicines Act. Note also that the definition in the original Regulation (GNR 1160 of 2000) referred, erroneously, to the "Medicine Act".	
6.				Consideration be given to including the definition of a "dispensary"and a "medicine room" in the Regulations, so as to allow for their use, both in terms of maintenance of registers and in terms of the Practice Regulations. The Good Pharmacy Practice standards (4th edition, 2010) describe the types of pharmaceutical premises other than a pharmacy as follows (section 1.6.2): "In a primary health care clinic where: (a) the services are provided by a pharmacist's assistant (post-basic) there must be a suitable room assigned for use as a **dispensary**; (b) the services are provided by a licensed dispenser in the consulting rooms in the primary health care clinic there must be a suitable room designated as a **medicine room** for use as a storage area for medicine. Pharmacies are licensed by the Department of Health, and recorded as such by the SAPC. They are therefore subject to periodic inspection and held to the requisite standards. If the dispensary operated by a PT under "indirect personal supervision" is to be appropriately regulated, it too should fall within the ambit of the inspection powers of the SAPC. That medicines rooms, whether located in a PHC clinic or the practice of a licensing dispensing practitioner, are outside of the control of the SAPC is a legal lacuna which still needs attention.	Consider adding a definition as follows: **"dispensary" means a suitable premises, approved by Council, in which a pharmacy technician working under the indirect personal supervision of a pharmacist provides a limited pharmaceutical service in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;**
7.	36			The inclusion of a short title for a set of amended regulations seems superfluous, and could be deleted.	Delete regulation 36 "Short title"

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) (GoN 657)

Comment no.	**Regulation, subregulation or paragraph**			**Comments and Rationale**	**Proposed Revised Text** **Bold underline** – additions **[square brackets bold]** – deletions
	Reg	Sub reg	Par		
1.	2	(a)		The addition of GPP compliance to the definition of "direct personal supervision" is welcomed. However, attention is drawn to the requirements of sections 22A(4) and (5) of the Medicines Act, which required "personal supervision".	Nil – requires clarification of the apparent conflict with the Medicines Act.
2.	2	(b)		The same point is made with regard to "indirect personal supervision", which appears at first glance to contradict the meaning of "personal supervision" in the Medicines Act. Supervision as intended in the Medicines Act goes beyond "guidance and support".	Nil – requires clarification of the apparent conflict with the Medicines Act
3.	2	(b)		In order to comply with the constitutional imperative of non-discrimination, and ensure that all patients and caregivers, whether receiving a pharmaceutical service in the public or private sectors, are treated equitably and receive the same protection under the law, the question of how to enable "indirect personal supervision" needs to be considered. The current definition of "primary care clinic" has not been amended, and reads "means an institution, facility, building, or place where persons receive primary health care treatment, diagnostic or therapeutic interventions or other primary health care services that is owned or controlled by an organ of State". Once NHI is implemented, Contracting Units for Primary Health Care will include private providers (as per section 37 of the NHI Bill, Bill 11 of 2019). It is therefore feasible that comprehensive PHC clinics may not be "owned or controlled by an organ of State" and yet be integral to the delivery of PHC services. It is insufficient to merely add, as sub-regulation 2(b) does that "any other facility as approved by the council" may employ indirect personal supervision as a means to addressing the need for pharmaceutical services. If	'indirect personal supervision' means guidance and support provided by a pharmacist to pharmacy support personnel in a **dispensary approved by council and located 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; In addition, to amend the definition of "primary health care clinic" as follows: "primary health care clinic" means an institution, facility, building, or place where persons receive primary health care treatment, diagnostic or therapeutic interventions or other primary health care services, **as defined in the National Health Act, but excludes a community**

				the logic is that a dispensary in a PHC clinic which operates in terms of a restricted medicines list and standard treatment guidelines (whether the current NDOH STG/EML or a future NHI formulary) can safely be managed by a PT under "indirect personal supervision", then those should be the criteria applied, regardless of ownership. It is also necessary to distinguish between a PHC clinic and a community health centre (CHC), which offers a higher level of service and usually includes medical practitioners in addition to PHC nurse prescribers. It is recommended that the existence of a dispensary is approved by SAPC, and that such pharmaceutical premises only be located within primary health care clinics. CHCs would therefore require a licensed and recorded pharmacy, under the personal supervision of a responsible pharmacist.	**health centre [that is owned or controlled by an organ of State]**; And to add: **"community health centre" means an institution, facility, building, or place where persons receive primary health care treatment, diagnostic or therapeutic interventions or other primary health care services, as defined in the National Health Act, and which includes a licensed and recorded pharmacy;** And to add, as above: **"dispensary" means a suitable premises, approved by Council, in which a pharmacy technician working under the indirect personal supervision of a pharmacist provides a limited pharmaceutical service in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;**
4.	2	(e)		For consistency either insert natural in front of person under the definition of pharmacy technician.	`pharmacy technician' means a **natural** person registered as such in terms of the Act
5.	2	(g)	(c)	Numbering of the sub-sub regulation has gone awry	Renumber (c) as (e) and create (f) for the last line "a course determined by the Council in terms of the Medicines Act (also see comment 4 above).
6.	3			The proposed amendment to Regulation 2 excludes compliance with GPP and the code of conduct. Is this deliberate, or is it considered to be subsumed in compliance with the Pharmacy Act? It is recommended that compliance with GPP be retained, as this emphasises the obligatory nature of good practice standards.	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, **rules relating to good pharmacy practice published in terms of section 35A of the Act,** and the Medicines Act.

7.	3			For consistency insert natural before person	Conditions under which services or acts must be provided or performed the services or acts pertaining to the scope of practice of **natural** persons registered in terms of the Act must be provided or performed in accordance with the Act and the Medicines Act.
8.	4	(1)		The reason for deleting sub-regulations 4(2) to (6) is unclear. At least some of the listed acts are not restricted to pharmacists alone (i.e. cannot be listed as acts "specially pertaining", but are nonetheless within the scope of practice of pharmacists. It is recommended that those not already covered by regulation 3 be retained. The repackaging of medicines falls within regulation 3(4), but is also subject to the requirements of General Regulation 39 issued in terms of the Medicines Act.	(1) the acts specifically pertaining to the profession of a pharmacist as prescribed in regulation 3; **(2) the initiation and conducting of pharmaceutical research and development; and** **(3) the promotion of public health.**
9.	5, 6, 7, 8			In the scopes of practice of interns and students, it is not immediately apparent that a distinction is being drawn between what can be done in a pharmacy other than that in which the intern or student is being trained and the pharmacy in which the intern's tutor is located or where a programme developed by the provider is executed. Nonetheless, the ability of interns and students to practise as pharmacist's assistants (including in the category of pharmacy technician) is welcomed. That such acts may only be performed under direct personal supervision is considered appropriate.	Nil – clarification needed
10.	8	(a)		No justification is provided for removing the ability to sell Schedule 1 medicines or scheduled substances from the scope of practice of a pharmacist's assistant (basic). Many PA(B) have been trained specifically for this role and are currently employed in pharmacies (specifically community pharmacies). They perform this act under direct personal supervision, in accordance with section 22A(4) of the Medicines Act.	**[(a) the deletion of subregulation (1)]** This will also require renumbering the the balance of the section, from (1) to (4).

11.	8	(a)	(5)	This provision needs to be brought into alignment with section 22A(14) of the Medicines Act.	[(5)](4) the distribution and control of stock of Schedule 1 to Schedule 5 medicines or scheduled substances**, excluding specified Schedule 5 medicines or substances**.
12.	10	(5)		This provision needs to be brought into alignment with section 22A(14) of the Medicines Act.	(5) the distribution and control of stock of Schedule 1 to Schedule **[6]5** medicines or scheduled substances**, excluding specified Schedule 5 medicines or substances**.
13.	10	(6)		This provision needs to be brought into alignment with section 22A(14) of the Medicines Act.	(6) the ordering of medicine and scheduled substances up to and including Schedule **[6]5** medicines or scheduled substances**, excluding specified Schedule 5 medicines or substances,** according to an instruction of a person authorised in terms of the Medicines Act to purchase or obtain such medicines or scheduled substances.
14.				Regulation 12 of the original regulations (GNR 1158 of 2000) has not been amended, but needs to be addressed in order to (1) specify where a PA(PB) may operate under indirect personal supervision, and which prescriptions can be dispensed. In particular, the provisions of sub-regulation 12(4) have not been stipulated in relation to the PT, as per the proposed regulation 13A (see comment 13 below)	
15.	12			Throughout the proposed regulation 13A, there is a failure to differentiate where the acts listed could be performed. Some are very specific to manufacturing pharmacies, and not to others. In addition, the inclusion of "packing and re-packaging" does not appear to take into account the requirements of General Regulation 39 issued in terms of the Medicines Act (unless performed within a registered manufacturing pharmacy). These provisions also need to be aligned with section 22A(14) of the Medicines Act, and preclude the involvement of pharmacy technicians (as a a category of	That sub-regulations 13A(1)(a) be separated so as to make it clear that (i) to (vi) should be performed only in a manufacturing pharmacy, and in accordance with standard operating procedures. That a separate sub-regulation be prepared to cover the assistance with compounding and preparation (not manufacture) of sterile or non-

				pharmacist's assistants) in "handling" specified Schedule 5 and Schedule 6 medicines and scheduled substances.	sterile medicines in a community or institutional pharmacy. Such compounding and preparation should be in accordance with section 14(4) of the Medicines Act and General Regulations 3 and 38. That sub-regulation 13A(1)(b) also state that acts listed in (i) to (iii) should be performed only in a manufacturing pharmacy, and in accordance with standard operating procedures. However, the restriction to Schedule 5, at a maximum, and excluding specified Schedule 5 needs to be incorporated. Further, that engagement in re-packaging in a community or institutional pharmacy only be done in accordance with General Regulation 39 issued in terms of the Medicines Act. That sub-regulation 13A(10(c) should be performed only in a manufacturing pharmacy, and in accordance with standard operating procedures. That sub-regulation 13A(10(d) should be performed in a manufacturing pharmacy, and in accordance with standard operating procedures. Consideration could be given to including wholesale and institutional pharmacies, but restricted to a maximum Schedule 5, excluding specified Schedule 5.

					Sub-regulation 13A(1)(f) seems to repeat provisions in (d) and (e), but also needs to be brought into alignment with section 22A(14), by limiting to Schedule 5, excluding specified Schedule 5.
16.	12	(1)	(e), (f) and (g)	The preamble to the proposed sub-regulation 13A indicates that these acts will be performed under "direct personal supervision" of a pharmacist. It is therefore difficult to understand what is meant by "validated" in (f) or to accept the supervisory role assigned in (e) to a PT. It is therefore suggested that sub-regulation (e) be deleted in its entirety. Sub-regulation (f) can then be renumbered, and amended as shown. Likewise, sub-regulation (g) is covered by the proposed amendment to (f) and can be deleted.	**[(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)]<u>(e)</u>** assisting with the management of stock of Schedule 1 to Schedule **[6] <u>5</u>** medicines or scheduled substances**<u>, excluding specified Schedule 5 medicines or scheduled substances, in a wholesale, institutional or community pharmacy.</u>[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;]**
17.	12	(1)	(h)	The way in which this sub-regulation is worded is in conflict with section 22A(4) and (5) of the Medicines Act, as both require the pharmacist's assistant to sell Schedule 1 and 2 medicines and	(h) the sale of Schedule 1 and Schedule 2 medicine without the prescription of an authorised prescriber, **<u>in accordance with section 22A(4) and (5) of the Medicines Act</u>**

				scheduled substances under the personal supervision of a pharmacist.	[**Provided that the supply of a Schedule 2 medicine takes place in consultation with a pharmacist];**
18.	12	(1)	(i)	This sub-regulation needs to be aligned with section 22A(14) of the Medicines Act.	(i) the dispensing of Schedule 1 to Schedule **[6] 5** medicine or scheduled substances**, excluding specified Schedule 5 medicines 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:
19.	12	(1)	(k)	Given that the entire list of acts in the proposed regulation 13A is "under direct personal supervision", the inclusion of a supervisory role for the PT is unworkable. Other pharmacist's assistants will also have to practise under direct personal supervision of a pharmacist. It is recommended that this sub-regulation be deleted and the balance renumbered.	**[(k) supervision of other pharmacist's assistants. as specified by the responsible pharmacist; and]**
20.	12	2		As the term "indirect personal supervision" is defined, that can be used in sub-regulation 13A(2). The same reasoning applied in comment 3 above could also be applied. However, as indicated, the potential conflict with the Medicines Act needs to be clarified first.	(2) Subject to subregulation (3), a pharmacy technician may provide or perform the following services or acts under the **indirect personal supervision** [**supervision]** of a pharmacist **[who may not be physically present]** in a **dispensary approved by council and located in a** primary health care clinic **[or other facility as approved by the council];**
21.	12	2	(a) and (b)	These sub-regulation need to be aligned with section 14(4) of the Medicines Act.	(a) The ordering of Schedule 1 to Schedule [**6]5** medicines or scheduled substances**, but excluding specified Schedule 5 medicines or**

					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]5** medicines or scheduled substances**, but excluding specified Schedule 5 medicines or substances: [Provided that orders received that contain Schedule 6 are validated by a pharmacist]**;
22.	12	2	(c), (d) and (e)	These sub-regulations can be amended to anticipate the changes under NHI, but combined. However, it is recommended that compounding not be included, as this would be in conflict with section 14(4) of the Medicines Act.	**(c) dispense [receive and screen]** prescriptions for medicine**s** which appear**[s]** on the national Primary Health Care Essential Medicines List **or applicable formulary** and which **[is] are** prescribed in accordance with Standard Treatment Guidelines**, including receiving and screening such prescriptions, [(d)]** the selection **or [,]** manipulation **[or compounding]** of **the** medicine prescribed, the labelling and packing of the medicine in an appropriate container, **and [(e)]** the provision of information to a patient, caregiver or the agent of a patient about **the** medicine dispensed**;**
23.	12	2	(e) and (f)	These sub-regulations allow the pharmacy technician under the supervision of a pharmacist who is not physically present to supply information about the medicine dispensed to a patient and/or caregiver. Pharmacy technicians training is not sufficient to equip them to perform phase 3 of dispensing (Provision of information and instructions to the patient to ensure the safe and effective use of medicine) and should be limited to the instructions on how to use the medicine. The sub-regulations should therefore be amended to prevent any confusion.	(e) the provision of **instructions** to a patient, caregiver or the agent of the patient about medicine dispensed. (f) the provision of **instructions** to a patient, caregiver or the agent of the patient about medicine which have been dispensed at a pharmacy and sent to the primary health care clinic or other facility as approved by Councill for supply to the patient or the patient's agent or caregiver.

24.	12	2	(g)	Although a PT operating under indirect personal supervision may be able to manage a dispensary (as defined in comment 3 above), it would be inappropriate for such a person to manage the medicine room which is relied upon by a licensed dispensing practitioner (as defined in GPP).	(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
25.	13	(1), (2)	(a) and (b)	There are concerns about the increase in the number of pharmacy support personnel that may be supervised by a pharmacist. There is also no differentiation in the proposed regulation 14 for the difference between direct and indirect personal supervision. It is noted that regulation 15 remains in place, allowing for written application to exceed the maxima stated. It is also noted that regulation 12(4) has not been amended. An unresolved issue is whether the maxima stated for direct and indirect personal supervision can be combined. In other words, whether a pharmacist supervising the maximum number of pharmacy support personnel in a pharmacy (and perhaps serving as tutor to an intern) may also, simultaneously supervise up to 5 PTs indirectly. Although the restriction on pharmacists who tutor interns at an educational institution is supported, it is unclear how they would ever supervise pharmacy support personnel in such settings. Nonetheless, the wording is retained.	To replace regulation 13 in the proposed regulations with the following: **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 three pharmacy support personnel under his or her direct personal supervision; provided that a pharmacist who is the tutor to a pharmacist intern may have a maximum of 2 pharmacy support personnel under his or her supervision, of which only one may be a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), pharmacy technician (learner) or pharmacy technician (trainee).** **(2) Subject to regulations 12 and 13A, a pharmacist may have a maximum of five pharmacists' assistants (post-basic) or pharmacy technicians under his or her indirect personal supervision.** **(3) A pharmacist who is a tutor of a pharmacist intern undergoing an internship at a provider of an education and training programme**

					<u>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.</u>
26.	14			The inclusion of a short title for a set of amended regulations seems superfluous, and could be deleted.	Delete regulation 14 “Short title”

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) (GoN 658)

Comment no.	**Regulation, subregulation or paragraph**			**Comments and Rationale**	**Proposed Revised Text** **Bold underline** – additions **[square brackets bold]** – deletions
	Reg	Sub reg	Par		
1.				A definition of "primary care drug therapy", which has been amended in GoN 657 will need to be amended in GNR 1156 of 2000 as well. In addition, consideration could be given to amending the definitions of "manufacturing pharmacy" and "wholesale pharmacy" to exclude mention of sale to "an organ of State" as this is in conflict with section 22A of the Medicines Act. The state is bound by both the Medicines and Pharmacy Acts.	Include amended definitions as in GoN 657.
2.				The definition of "contract" has omitted pharmacy technician (learner)	'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 **pharmacy technician (learner); or** (c) traineeship of a pharmacy technician (trainee)
3.				The definition of "tutor" has omitted pharmacy technician (learner)	`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) **or pharmacy technician (learner)**;
4.	11			No reason for deleting regulation 9 is provided.	Nil – clarification needed.
5.	12	(c), (d)		This sub-regulation seems to imply that the pharmacist who supervises the intern at a community or institutional pharmacy during the 400-hour exposure must also be registered as a tutor. Does this imply that an intern in a manufacturing or wholesale pharmacy (see comment 2 above) will need to have two registered tutors, and two independent contracts? Or must the supervising pharmacist at the community or institutional pharmacy have to be a registered tutor to another intern? Both would seem to pose practical barriers and could be reconsidered.	Nil – clarification needed.
6.	27			The category pharmacy technician (learner) has been omitted from Regulation 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 pharmacists assistant (learner basic) or pharmacist's assistant (learner post -basic) **or pharmacy technician (learner)**: 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
7.	28			Clarity is required in Regulation 25 regarding the period of in-service training for each exit point of the occupational certificate is needed.	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 consisting of;

					a) 6 months for a pharmacist's assistant (basic); **b) 12 months for a pharmacist's assistant (post-basic); and** **c) 18 months for a pharmacy technician.**
8.	30			There is no motivation supplied as to why Regulation 28 has been deleted. The delegation of in-service training is a necessary instrument during the training of assistants in the pharmacy. There are many situations where the training is delegated to a pharmacist who works in a different department or section of the pharmacy than the tutor. This ensures a holistic approach to training. The Regulation should therefore be retained.	**28. Delegation of in-service training.—A tutor may delegate the actual in-service training of a pharmacist's assistant to another pharmacist practising in a full-time capacity in the same pharmacy: provided that the tutor will be responsible to ensure that the in-service training is completed in accordance with the provisions of these regulations and that council is informed in writing of such delegation.**
9.	31			Regulation 30 needs to be aligned with regulation 14 of the Practice regulations (as amended by the proposed changes in GoN 657).	The maximum number under supervision should not exceed 3, except with the permission of council. The limit would be reduced if the pharmacist is also a tutor to an intern (see comment 22 above)
10.	31			The category pharmacy technician (learner) has been omitted from Regulation 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 pharmacists assistants (learner post- basic) **or pharmacy technicians (learner)**, per category or a combination thereof, undergoing in- service training.
11.	32			The category pharmacy technician (learner) has been omitted from Regulation 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) **or pharmacy technician (learner)**, 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.
12.	33			The category pharmacy technician (learner) has been omitted from Regulation 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) **or pharmacy technician (learner).**
13.	35	34I		The maximum number of PT (trainees) needs to take into account the number of interns and other pharmacist's assistants (learner) that are supervised simultaneously.	Align with regulation 30 and also regulation 14 of the Practice regulations.
14.	39			See comment 3 above regarding the need to register providers of CPD	Consider deletion of sub-regulation 41(1)(c). renumber the balance, but add a number for the last line (as before).
15.	41			In the proposed sub-regulation 42A(1) it is not clear that the "designated pharmacist" appointed by an educational institution would have a suitable leadership role at that institution. The contrast with provisions of Good Pharmacy Education Standards (Board Notice 83 of 2017), which states: "2.1.1 Qualifications of the head • The head must be qualified to provide leadership in pharmacy professional education and practice, including research, scholarly activities and service. • They must unite and inspire administrators, faculty, staff, mentors and students toward achievement of the mission and goals." The provisions of the suggested sub-regulation (3) are insufficient. In particular, unless the designated pharmacist has a suitable leadership position s/he cannot take the corrective actions demanded in sub-regulation 3(g).	It is recommended that the head be identified as the designated pharmacist, and that such a person should be registered as a pharmacist in South Africa.

16.	42			Regulation 43 previously required that educational providers be inspected at least every 3 years “or at intervals as determined by council”. No justification for removing the indicative standard has been provided.	Retain the deleted wording.
17.	45			The inclusion of a short title for a set of amended regulations seems superfluous, and could be deleted.	Delete regulation 45 “Short title”