KENYA PHARMACEUTICAL ASSOCIATION

Pharmaceutical Excellence

Kenya Pharmaceutical Association (KPA).
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Our Ref: KPA/NEC/GPP/02 Date: 31/8/2026

INTERNAL MEMO

Dear Esteemed KPA Members,

RE: KPA POSITION ON THE EMERGING GOOD PHARMACY PRACTICE (GPP) GUIDELINES AND THE ROLE OF PHARMACEUTICAL TECHNOLOGISTS IN LEVEL 3 FACILITIES

The Kenya Pharmaceutical Association (KPA) remains committed to advancing the pharmacy profession, protecting the legitimate professional interests of its members, promoting responsible self-regulation, and safeguarding the public's right to safe, accessible, equitable and quality pharmaceutical care. Our position has consistently been that regulation must strengthen healthcare delivery rather than create artificial barriers to the utilization of appropriately trained and legally recognized health professionals.

The Association has taken keen note of the recent emergence and apparent launch of **Draft 11 of the Good Pharmacy Practice (GPP) Guidelines** during the recent Health Summit, particularly the provision that effectively removes **Pharmaceutical Technologists from the position of superintendent in Level 3 hospital facilities and the handling, management and professional responsibility relating to narcotic and psychotropic medicines.**

This development is of grave concern to the Association, And publics access to pharmaceutical care.

1. KPA DID NOT PARTICIPATE IN THE DEVELOPMENT OF DRAFT 9, 10 AND DRAFT 11

For clarity, KPA's formal participation in the GPP review process was up to **Draft 8.** At the GPP stakeholders' workshop convened during that process, the Association was represented by the **entire National Executive Council (NEC).**

The workshop was not without disagreement. KPA openly protested and rejected several proposals that were considered discriminatory, professionally exclusionary and inconsistent with the realities of pharmacy practice and healthcare delivery in Kenya.
Importantly, KPA was subsequently accorded an opportunity to make a **detailed submission on the GPP Guidelines,** and the Association was assured that its submissions would be considered in the subsequent review.

It is therefore deeply concerning that the process appears to have progressed from Draft 9 to Draft 11 without the Association's meaningful participation, representation or opportunity to validate the substantial amendments that have subsequently emerged.

Accordingly, **KPA does not recognize itself as a participant in, nor does it endorse or assume ownership of, Draft 10 or Draft 11**. The presence of the Association's name among contributors to an earlier stage of the process cannot reasonably be construed as endorsement of a substantially amended document developed without the Association's participation.

We have also noted that several other individuals and stakeholders who contributed significantly to the development of the earlier drafts do not appear to be reflected in the latest version. This raises legitimate questions regarding the transparency, inclusivity and governance of the finalization process.

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2. THE EXCLUSION OF PHARMACEUTICAL TECHNOLOGISTS IS UNACCEPTABLE

The proposed exclusion of Pharmaceutical Technologists from superintending Level 3 hospital facilities cannot be viewed merely as an administrative amendment. It has direct implications for **professional recognition, employment opportunities, health-system staffing and access to pharmaceutical services**.

Kenya's pharmaceutical workforce is not composed exclusively of pharmacists. The national Health Worker Registry currently lists approximately **2,738 pharmacists and 9,927 Pharmaceutical Technologists,** demonstrating the substantial contribution of the latter cadre to the country's pharmaceutical workforce.
At the same time, Kenya continues to operate a very large and geographically dispersed health system.

The Ministry of Health has reported that more than **11,800 Level 2 and Level 3 facilities** are central to the country's primary healthcare and Universal Health Coverage agenda.
It is therefore difficult to reconcile a health-system objective of expanding access to care with regulatory measures that unnecessarily narrow the pool of appropriately trained professionals who can take responsibility for pharmaceutical services at these facilities.

A regulatory framework that excludes a substantial and legally recognized pharmaceutical cadre from legitimate leadership responsibilities must demonstrate a compelling, evidence-based public-health justification. Professional exclusion for its own sake cannot be accepted as a substitute for patient safety.

3. REGULATION MUST NOT BECOME PROFESSIONAL EXCLUSION

KPA fully supports regulation, accountability, patient safety, quality assurance and continuous professional development. We equally recognize the importance of Kenya aligning its regulatory and pharmaceutical systems with appropriate international standards and best practices.

However, **international standards cannot be adopted through a copy-and-paste approach that disregards Kenya's own health-system realities, workforce structure and service-delivery needs.**

The Association is aware of concerns that some of the hurried policy and regulatory changes currently being advanced within the pharmaceutical sector are being undertaken, at least in part, in the guise of preparing Kenya for or meeting **WHO ML3 certification requirements**.

KPA wishes to make its position unequivocally clear: ***we support Kenya attaining the highest possible standards of regulatory maturity, including the attainment of WHO ML3 status. However, ML3 certification must not become a convenient justification for importing regulatory models that are disconnected from Kenya's unique healthcare realities or for retrospectively imposing professional restrictions that have not been adequately consulted upon or demonstrated to improve patient outcomes.***

International standards should inform our systems; **they should not erase our context.**

Kenya has its own disease burden, health-system architecture, workforce distribution, facility structure, economic realities and access-to-care challenges. What may be appropriate in a different jurisdiction cannot automatically be transplanted into Kenya without examining its consequences within our own health system.

KPA strongly advocates for a "local solutions for local problems" approach - one that draws from international best practice while adapting it intelligently to Kenya's circumstances.

Regulation should therefore answer a fundamental question: **does the proposed change make pharmaceutical care safer, more accessible and more effective for the Kenyan patient?**

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If a regulatory intervention achieves international conformity on paper while creating workforce shortages and restricting access to pharmaceutical services on the ground, then its practical value must be questioned.

Regulation must be evidence-based, proportionate, transparent and non-discriminatory.

The Pharmacy and Poisons Act assigns the PPB significant responsibilities in regulating pharmacy practice.

KPA's concern, therefore, is not whether pharmacy should be regulated. **It must be regulated.**

Our concern is whether regulatory decisions are being developed through an adequately consultative process, whether they are consistent with the wider health-sector human-resource framework, whether they are supported by evidence, and whether they advance rather than undermine access to pharmaceutical care.

The Association will consequently interrogate the legal, policy and technical basis upon which the latest provisions have been introduced.

4. THE NUMBERS TELL A DIFFERENT STORY

The current composition of Kenya's licensed pharmaceutical workforce further demonstrates why the proposed exclusion of Pharmaceutical Technologists from superintending Level 3 facilities requires serious reconsideration.

According to the **2026 professional workforce figures available to the public from the PPB,** Kenya has approximately registered 5,000 Pharmacists and enrolled 14,000 Pharmaceutical Technologists, out of which **15,397 licensed pharmaceutical professionals,** comprising:

- **10,533 Pharmaceutical Technologists;**
- **2,931 Pharmacists; and**
- **1,933 Pharmaceutical Representatives.**

Pharmaceutical Technologists therefore constitute by far the largest professional cadre within the licensed pharmaceutical workforce.

At the same time, Kenya has approximately **2,559 Level 3 health facilities**. These figures present a simple but fundamental health-system question: **how can a policy realistically require approximately 2,559 Level 3 facilities to be superintended exclusively by a pharmacist workforce of approximately 2,931,** (on workforce ratio basis) while simultaneously excluding the much larger cadre of 10,533 Pharmaceutical Technologists?

This is not merely a professional-interest argument. It is a question of **health-system mathematics, workforce planning and access to care.**

Even before accounting for pharmacy professionals required in Level 4, Level 5 and Level 6 hospitals, specialized services, industry, academia, regulatory institutions, research, wholesale and other areas of practice, the numbers make an exclusively pharmacist-dependent superintendency model for Level 3 facilities **operationally impractical and potentially unsustainable** *noting there exists (on face value) about 5,000 registered Pharmacists against 14,000 Pharmaceutical Technologists.*

A policy that appears technically elegant on paper but cannot be realistically implemented because it ignores the actual composition of the country's health workforce risks becoming **a plastic policy; rigid in wording but detached from the practical realities it is intended to regulate.**

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KPA therefore urges the regulator and policymakers to interrogate the evidence carefully: **regulation must be designed around the health system that Kenya actually has, not an idealized workforce that Kenya does not possess.**

The 10,533 Pharmaceutical Technologists currently forming the backbone of pharmaceutical service delivery across the country cannot simply be regulated out of legitimate leadership responsibilities without a compelling, evidence-based justification.

5. THE PUBLIC INTEREST MUST REMAIN THE CENTRE OF REGULATION

The Association's position goes beyond the professional interests of one professional cadre - Pharmaceutical Technologists.

Kenya faces a persistent challenge of ensuring adequate health-worker distribution, particularly outside major urban centers. The Ministry of Health's health-sector assessment continues to identify significant staffing shortages across Level 2 and Level 3 facilities.

In this environment, Kenya cannot afford regulatory frameworks that unnecessarily restrict the utilization of competent and appropriately trained pharmaceutical personnel.

Our responsibility as a professional association is therefore twofold: to protect the legitimate rights and Professional dignity of Pharmaceutical Technologists and, equally importantly, to protect the Kenyan public from regulatory decisions that may inadvertently reduce access to pharmaceutical services.

Every unnecessary professional barrier has the potential to become a barrier to patient access.

Kenya's healthcare system requires an appropriately distributed, competent and adequately utilised health workforce. Level 3 facilities constitute a critical part of primary and community-level healthcare delivery, particularly as Kenya continues to pursue Universal Health Coverage and strengthen access to services closer to where people live.

With **2,559 Level 3 facilities** serving communities across the country, excluding the country's largest pharmaceutical professional cadre from superintending roles has consequences that extend beyond employment or professional recognition.

It potentially affects: **availability of pharmaceutical services; continuity of care; geographic access; facility functionality; workforce distribution; and ultimately patient outcomes.**

KPA therefore challenges any regulatory approach that treats professional exclusion as an automatic proxy for improved quality.

Quality is achieved through competence, appropriate training, accountability, supervision, continuous professional development, effective regulation and measurable standards - not simply by substituting one professional title for another.

Where a Pharmaceutical Technologist possesses the prescribed qualifications, experience and competence to undertake a responsibility safely and effectively, the regulatory question should be based on **competence and public protection**, rather than an assumption that exclusion of the cadre inherently improves quality.

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6. INTERNATIONAL STANDARDS MUST WORK FOR KENYA
KPA reiterates that it is not opposed to international standards, WHO requirements or regulatory maturity. Indeed, Kenya should aspire to the highest standards possible.

However, **international recognition should be the outcome of a strong Kenyan regulatory system, not the reason for disregarding the Kenyan health system.**

WHO ML3 certification, or any other international benchmark, must be pursued in a manner that strengthens rather than weakens Kenya's capacity to deliver pharmaceutical services.

The Association therefore calls for a balanced approach in which international standards are **contextualized, localized and implemented through evidence-based Kenyan solutions**.

We cannot afford a situation where Kenya achieves compliance with an international benchmark while simultaneously creating regulatory barriers that reduce the country's capacity to deploy its available pharmaceutical workforce.

Local problems require locally intelligent solutions.
Kenya should develop a regulatory framework that is internationally credible, nationally appropriate and practically implementable.

7. NARCOTIC AND PSYCHOTROPIC MEDICINES: ACCESS MUST NOT BE SACRIFICED THROUGH PROFESSIONAL EXCLUSION
The Association is equally concerned by provisions in the final draft that effectively **reserve the handling, management and professional responsibility relating to narcotic and psychotropic medicines exclusively to pharmacists,** thereby unnecessarily limiting the role of Pharmaceutical Technologists in the provision of essential pharmaceutical services.

KPA considers such blanket professional reservation to be **discriminatory, disproportionate and potentially detrimental to access to essential medicines,** particularly in settings where Pharmaceutical Technologists constitute the majority of the available pharmaceutical workforce.
The safe management of narcotic and psychotropic medicines is undoubtedly a matter requiring stringent controls, professional accountability, appropriate documentation, secure storage, traceability and effective regulatory oversight. **KPA does not advocate for weakened controls.** On the contrary, we support robust safeguards commensurate with the risks associated with these medicines.

However, **patient safety should be secured through competency-based regulation and effective systems of accountability, not through arbitrary exclusion of an entire professional cadre.**
Where appropriately trained, licensed and competent Pharmaceutical Technologists are lawfully providing pharmaceutical services, their blanket exclusion from functions relating to essential controlled medicines requires clear scientific, operational and public-health justification.

This is particularly important in a country where Pharmaceutical Technologists number **14,000 compared with 5,000 pharmacists**. Reserving critical pharmaceutical services exclusively to pharmacists in a health system with **Over 10,000 registered premises – 8,000 plus community pharmacies, 8,806 Level 2 facilities, 2,559 Level 3 facilities, 971 Level 4 facilities, 34 Level 5, 5 Level six and over 1,050 Faith Based Organization facilities,** Industry, programs, risks creating artificial workforce constraints, particularly in underserved and rural areas where access to pharmacists may already be limited.

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The consequence could be particularly serious for patients requiring essential medicines for pain management, palliative care, mental health and other conditions for which controlled medicines may be clinically indicated.

A regulatory framework should never make a medicine legally available in principle but practically inaccessible because the health system has unnecessarily restricted the category of professionals capable of facilitating its lawful and safe access.

KPA therefore rejects any approach that uses the legitimate need for control of narcotic and psychotropic medicines as a basis for blanket professional exclusion. The appropriate approach is to establish **clear competency requirements, defined responsibilities, robust supervision, continuing professional development, accountability mechanisms and appropriate safeguards**, rather than simply reserving functions on the basis of professional title.

The Association will advocate for a regulatory framework that protects the public from diversion, misuse and unsafe handling of controlled medicines while simultaneously ensuring that patients are not denied or unnecessarily delayed access to essential pharmaceutical services.
Public protection and professional inclusion are not mutually exclusive. A mature regulatory system must achieve both.

8. KPA'S POSITION ON DRAFT 11: THE ASSOCIATION DOES NOT ENDORSE THE FINAL DRAFT
Having considered the circumstances surrounding the evolution of the GPP Guidelines, the exclusion of the Association from substantive engagement after Draft 9, the introduction of provisions that materially affect the professional role of Pharmaceutical Technologists, the proposed restrictions concerning Level 3 facility superintendency, the reservation of functions relating to narcotic and psychotropic medicines, and the broader implications of the document for access to pharmaceutical services, **KPA wishes to state its position unequivocally.**

The Kenya Pharmaceutical Association Rejects Draft 11 of the Good Pharmacy Practice Guidelines in its entirety.

This rejection is not limited to one clause or one professional-interest issue.
It is a rejection of the **final draft as a whole in its present form**, arising from concerns regarding the process through which it has evolved, the lack of meaningful KPA participation in its subsequent development, the substantive provisions that unjustifiably restrict the role of Pharmaceutical Technologists, the potential inconsistency with the realities of Kenya's health workforce, and the possible consequences for access to healthcare.

KPA cannot selectively endorse a document whose subsequent amendments were undertaken without the Association's participation and which now contains provisions that fundamentally alter the professional and operational environment within which our members practice.

We therefore disown and reject the final Draft 11 in its entirety and do not consider it to represent a document developed with the consent, participation or endorsement of the Kenya Pharmaceutical Association.

This position should not be misconstrued as opposition to Good Pharmacy Practice, professional standards or effective regulation.

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KPA remains a strong advocate of Good Pharmacy Practice.
What we reject is a GPP framework that is developed without adequate participation of key stakeholders, departs from the realities of Kenya's pharmaceutical workforce, creates unnecessary professional barriers, and potentially undermines rather than advances access to pharmaceutical care.

The Association is prepared to participate constructively in a **fresh, transparent, inclusive and evidence-based review process** that brings all relevant stakeholders back to the table and subjects the proposed provisions to proper technical, legal, workforce and public-health scrutiny.

Until such a process is undertaken, **KPA cannot associate itself with, endorse, defend or accept Draft 11 as the Association's position or as a legitimate reflection of the consensus of the pharmacy profession.**

Our rejection is therefore both **professional and institutional.**
We reject provisions that are discriminatory.
We reject provisions that are unsupported by adequate evidence.
We reject provisions that unnecessarily restrict the utilization of Kenya's available pharmaceutical workforce.
We reject provisions that may create avoidable barriers to access to essential medicines and pharmaceutical services.
And we reject a process in which substantive changes can be introduced after the exclusion of key stakeholders and subsequently presented as an agreed professional framework.

KPA stands ready to engage; but we will engage from a position of professional integrity, evidence and fidelity to the public interest.

9. OUR NEXT STEPS
The Association has already taken note of the developments and has commenced **wide-ranging internal and external consultations**.

These consultations will examine, among other matters:

- The evolution of the GPP Guidelines from Draft 9 to the current version;
- The extent and nature of stakeholder participation in the subsequent drafts;
- The legal and regulatory basis for the proposed exclusion of Pharmaceutical Technologists from superintending Level 3 facilities;
- Consistency of the proposed provisions with national health-sector human-resource policies and staffing frameworks;
- The implications of the provisions for healthcare access, workforce availability and patient safety; and
- Appropriate professional, administrative, policy and legal avenues available to safeguard the interests of members and the public.

KPA will engage the relevant authorities and stakeholders constructively, firmly and through all appropriate channels.

Our objective is not confrontation for its own sake. Our objective is accountability, fairness, professional recognition and a regulatory framework that works for Kenya.
Members are therefore urged to remain calm, united and vigilant and to avoid relying on unverified information or engaging in unnecessary personal attacks against individuals or institutions.

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10. KPA WILL NOT REMAIN SILENT

The Association has taken keen note of the trajectory of the GPP review process and the apparent changes introduced after the Association's participation in Draft 8.

We are particularly concerned where subsequent changes appear to systematically narrow the legitimate professional space of Pharmaceutical Technologists without adequate consultation, evidence or transparent justification.

KPA will not accept a process in which its participation at one stage is subsequently used to confer legitimacy upon substantial amendments to which the Association was neither consulted nor party.

The Association is aware of the implications of these developments, the interests that may be advanced through them, and the potential consequences for both the pharmaceutical workforce and the Kenyan public.

We shall therefore vigorously defend the professional rights of Pharmaceutical Technologists while remaining firmly anchored on patient safety, public interest and the constitutional objective of progressive access to healthcare.

Our response will be **measured, strategic, evidence-based and decisive.**

We are consulting widely within the profession, across relevant health-sector stakeholders and with appropriate external partners to establish the most effective course of action.

KPA will not allow international standards to be **weaponized** against local professionals. We will not allow regulatory reform to become professional exclusion. And we will not allow policies developed without adequate regard to Kenya's realities to compromise access to pharmaceutical care.

Our commitment remains clear:

Internationally benchmarked.
Kenyan in context.
Evidence-based in implementation.
Patient-centred in outcome.

KPA will not allow the professional contribution of Pharmaceutical Technologists to be diminished through regulatory changes developed without meaningful participation of the affected cadre.

We shall continue to advocate for a pharmacy regulatory framework that recognizes the realities of Kenya's health workforce, protects professional competence, promotes accountability and, most importantly, **expands rather than constrains access to quality pharmaceutical care for the Kenyan people**.

We call upon all members to remain united and to place confidence in the Association as we pursue this matter through the appropriate professional, policy, administrative and legal channels.

The Association will communicate the outcome of the ongoing consultations and the agreed **way forward as soon as practicable**.

Yours sincerely,

Eric Gichane
Hon. Secretary General
Kenya Pharmaceutical Association

Chitechi Amboka
Hon. President
Kenya Pharmaceutical Association