Access or excess? Peptide manufacturing pharmacies at the fault line of South African pharmacy professionalism

If you listen carefully to how members of the pharmacy profession within South Africa is speaking about itself now, a pattern emerges. In this edition you will learn that hospital colleagues are writing about evolution from basements/dispensaries to the bedside, about stewardship, innovation and learning from the giants who came before them. Young pharmacists are insisting that relevance and purpose matter more than where on the programme their session appears, and are asking older pharmacists and mentors, hard questions about mentorship, digital health and leadership. Educators are reflecting deeply on how we shape professional identity, not only competence, under conditions of uncertainty and constraint. I believe this will be a constant, the uncertainty and constraint as change is a constant; what matters ethically is not whether we can escape it, but whether we respond to it deliberately and responsibly, in ways that honour our obligations to patients, colleagues and the public.

Change in science and practice rarely arrives in a neutral form; it is carried concrete technologies, products and business models that test how serious we are about our own standards. Over the past two years, incretin-based peptides such as semaglutide and tirzepatide have moved from specialist diabetes clinics into the public imagination as weight-loss "super-drugs". They are now widely promoted as weight-loss injections on social media and offered in some private and aesthetic settings, including certain pharmacy spaces, despite repeated warnings about unregistered GLP-1 products sold via informal and online channels. Nowhere is this more visible than in the rapid rise of incretin-based therapies. What began as specialist tools for complex type 2 diabetes and high-risk metabolic disease has, in a few short years, become a powerful commercial force, reshaping **patient expectations** and placing new pressures on pharmacists, prescribers and regulators alike. It is in this tension between clinical promise, market enthusiasm and regulatory boundaries that the profession's ethical commitments are most clearly exposed.

A limited exception is created in section 14(4), read with regulation 3 of the General Regulations, which permits a pharmacist to compound a medicine for a specific, identified patient, on the basis of a valid prescription, in a quantity related to that individual's treatment and which does not amount to ongoing batch manufacture for the market. Section 14(4)(b) further requires that the active ingredient used in such compounding is already contained in at least one medicine registered in terms of the Act, and the regulatory literature is clear that compounding may not be used to circumvent the registration pathway. A limited exception is created in section 14(4), read with the General Regulations, which permits a pharmacist to compound a medicine for a specific, identified patient, on the basis of a valid prescription, in a quantity that is related to that individual's treatment and which does not amount to ongoing batch manufacture for the market. The same framework requires that the active ingredient used in such compounding is already contained in at least one registered medicine, and that compounding may not be used to circumvent the registration pathway.

Good Pharmacy Practice (GPP) and Good Manufacturing Practice (GMP) operate together, but they do not apply to the same activities. GPP is issued by the South African Pharmacy Council (SAPC) as *"Rules relating to Good Pharmacy Practice"* under section 35A of the Pharmacy Act 53 of 1974, and it sets the minimum standards for all pharmacy premises and services, including extemporaneous compounding. These rules require that any compounded medicine be prepared in suitable premises, using appropriate equipment, with documented standard operating procedures, quality-assurance systems, and full records, and they reiterate that extemporaneous preparations are exceptional, patient-specific and based on a valid prescription, not a mechanism for routine batch production. Extemporaneous compounding is further constrained by the Medicines and Related Substances Act 101 of 1965 and its General Regulations, which permit compounding only within the narrow exemption in section 14(4), for quantities related to an individual patient's treatment and using active ingredients that are already present in at least one registered medicine. By contrast, GMP, as defined in SAHPRA's South African Guide to Good Manufacturing Practice for Medicines, applies to licensed manufacturers of finished products, including sterile peptide injectables, and requires a level of validated process control, environmental monitoring and batch-release testing that goes well beyond what is envisaged for a pharmacy compounding unit.

SAHPRA is a participating authority in the Pharmaceutical Inspection Co-operation Scheme (PIC/S), which means South African manufacturers are expected to meet internationally aligned GMP standards.

Within this combined framework, a pharmacy that compounds occasionally for named patients is expected to comply with GPP and

with the compounding conditions in section 14(4) of the Medicines Act; it is not expected to operate to full GMP standards. However, once a pharmacy begins to prepare unregistered glucagon-like peptide-1 (GLP-1) receptor agonists or dual GIP/GLP-1 receptor agonist injections in bulk, for commercial distribution, it no longer fits within the legal definition of extemporaneous compounding. It is effectively functioning as a manufacturer without a manufacturing licence, without registered products under section 14(1), and without compliance with SAHPRA's GMP expectations. They are now widely promoted as weight-loss injections on social media and offered in some private and aesthetic settings, despite SAHPRA warnings about unregistered GLP-1 products sold through informal and online channels.

Within this combined framework, the routine preparation of unregistered glucagonlike peptide1 (GLP1) receptor agonists or dual GIP/GLP1 receptor agonist products in bulk, for commercial distribution, does not fall within lawful extemporaneous compounding; it is treated in law as the manufacture and sale of unregistered medicines in contravention of section 14(1) of the Medicines Act and outside both GPP and applicable GMP requirements.

SAHPRA's 2025 RC03 communication moves further in relation to incretin-based peptides. In that notice, the Authority announces its intention, in terms of section 23 of the Medicines Act, to declare medicines compounded under section 14(4) that contain GLP-1 active components, or combinations of GLP-1 and gastric inhibitory (glucose-dependent insulinotropic) polypeptide (GIP) agonist components, to be "undesirable", on the basis that their extemporaneous preparation is not in the public interest. In such circumstances, the legal position is not ambiguous, the entities involved are operating outside the compounding exemption, manufacturing unregistered medicines in contravention of the Medicines Act 101 of 1965 and breaching professional rules under the Pharmacy Act.

The SAPC Code of Conduct requires that the wellbeing of the patient and the public remain the pharmacist's prime concern, that professional independence be maintained, and that pharmacy professionals avoid perverse incentive arrangements that place self-interest or commercial gain above lawful, ethical, and safe practice.

In a strictly legal or commercial reading, patients appear primarily as *"demand drivers"* for weight-loss injections. In an ethical reading, they appear as people with complex histories of stigma, failed treatments, and often carry deep shame around obesity and metabolic disease. An empathetic posture recognises that such patients are particularly vulnerable to promises of "quick fixes" and may struggle to appraise risk in the face of hope. Ethical pharmacy practice, especially in a resource-constrained system, therefore, asks not only "can I provide this product?" but "what does it mean to offer this to this person, in this context, with this level of evidence uncertainty?". Empathy here is not sentimentality; it is a disciplined willingness to see the patient's vulnerability clearly, to recognise our own power in the interaction, and to act in ways that protect rather than exploit that vulnerability.

Bringing these strands together, a coherent ethical framework for South African pharmacy would include at least three commitments. First, *a deontological commitment* to the Code of Conduct and GPP, the patient's wellbeing and public health come before profit and convenience; we do not enter into perverse arrangements even when they are lucrative. Second, an *evidence-based commitment*, we do not manufacture, promote or dispense medicines whose quality, safety and efficacy have not been established through appropriate regulatory pathways, particularly when regulators have explicitly declared them undesirable. Third, an *empathy-infused, relational commitment* we refuse to turn patients' desperation and structural barriers to care into a market opportunity, and we consciously design our services, whether in obesity, diabetes or any other field to support dignity, informed choice and shared decision-making rather than dependency and risk. Not just lip service.

Seen through this ethical lens, the GLP-1/peptide story is not primarily about "bad apples" caught in a regulatory net. It is a stress test of our collective moral posture as a profession that prides itself on science, stewardship and patient-centred care. Our response will signal to our students, our colleagues and our regulators whether we are prepared to align our incentives with our ethics, and our practice with both the law and the people it is designed to protect.

At a system level, we need clearer, practical guidance on the regulatory status of peptide products, particularly biologics and dualagonist combinations. We need transparent, sciencebased criteria for when local manufacturing is in the public interest and what standards must be met. We need closer alignment between SAHPRA, SAPC, professional bodies and academic partners, so that policy, education and practice do not pull in different directions. At a practice level, pharmacy owners and responsible pharmacists must subject their own business models to honest scrutiny. Does this service align with GPP, our Code of Conduct and our commitments to safety and equity?

Crucially, we must not treat the current peptide debate as an isolated compliance problem. It is taking place in a profession that is simultaneously expanding its roles in primary health care within the mandate of the National Health Insurance (NHI). I believe the real question before us is not whether local peptide innovation is inherently good or bad. It is whether any such innovation is embedded in lawful, transparent resilient needsbased models that genuinely improve access without compromising safety or equity. In a country where so many still lack reliable access to essential medicines and dependable pharmaceutical care, we have to be precise about what we mean by "access". If it simply means that those with means can buy unregistered injectables from whoever is willing to sell them, then we have not advanced access at all; we have merely packaged excess in clinical language. We have to be resilient in a market that changes so quickly.

Taken together, the legal and regulatory framework leaves little room for ambiguity. Section 14(1) of the Medicines Act establishes registration as the norm for all medicines, with section 14(4) creating only a narrow, patient-specific compounding exception; section 14(4)(b) and the General Regulations make clear that this exception is

constrained in both quantity and active-ingredient choice. SAHPRA's RC03 notice and subsequent GLP-1 warnings have now explicitly closed this exception for GLP-1 and GLP-1/GIP agonist products by signalling an intention to declare them "undesirable" when compounded and by treating their bulk production and promotion as unlawful manufacturing and distribution of unregistered medicines. At the same time, the SAPC Code of Conduct and GPP rules oblige pharmacists and registered support personnel to put patient and public wellbeing first, maintain professional independence, comply with all applicable legislation and avoid perverse incentive arrangements that place personal or commercial gain above legal and ethical duties.

For South African pharmacy, the evidence therefore points in one direction: large-scale "compounding" and marketing of unregistered GLP-1 and GLP-1/GIP peptides for weight loss cannot be reconciled with the Medicines Act, SAHPRA's regulatory stance or the profession's own Code of Conduct. Whatever debates continue about access and innovation in diabetes and obesity care, they must occur within the framework of registered products, licensed manufacture and lawful, evidence-based practice if pharmacy is to retain its claim to stewardship, integrity and public trust.

Natalie Schellack
Editor: SA Pharmaceutical Journal