

**WRITTEN SUBMISSION
ON NHI BILL [B11-2019]**

**Mr Vincent Tlala
REGISTRAR
South African Pharmacy Council**



**South African
Pharmacy Council**
Accessible quality pharmaceutical services for all

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Getting to know the SAPC

- ▶ The South African Pharmacy Council is health statutory council established in terms of the Pharmacy Act, 53 of 1974 (the Act). Its objects, in terms of Section 3 of the Act, are, amongst others, to:
 - (a) to assist in the promotion of health of the population of the Republic;
 - (b) to advise the Minister of Health or any other person on any matter relating to pharmacy;
 - (c) to promote the provisions of pharmaceutical care which complies with universal norms and values, in both the public and private sector, with the goal of achieving definitive therapeutic outcomes for the health and quality of life of a patient; and
 - (d) to uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and private sector.

- ▶ **Our mission**

Our mission is to promote universal health coverage by ensuring excellent and sustainable patient-centred pharmaceutical services by developing, enhancing and upholding acceptable norms and standards in all spheres of pharmacy.



Getting to know the SAPC (concl.)

- ▶ For purposes of completeness and understanding of the role the SAPC plays in the management of health care service providers, it is important to note that the SAPC registers and records:
 - a. pharmacists;
 - b. pharmacy support personal, which includes pharmacist's assistants in various identified categories;
 - c. pharmacy owners, who may be natural or juristic persons and includes the State as owners of pharmacies operating in the public sector, as well as private owners; and
 - d. pharmacy premises, in both the public and the private sector.
- ▶ It is thus noted that the SAPC has a comprehensive footprint in the management of pharmacy professionals who practice in both the public and private sectors of our health system, as well as pharmacies providing pharmaceutical services in both the private and public sector.
- ▶ In addition, the SAPC is mandated, in terms of the Medicines and Related Substances Act, 101 of 1965, in particular sections 22A and 22C, to assist the Director-General: Health, by providing consultation pertaining to the issuing of permits in terms of Section 22A, and the approval of courses in respect of the issuing of dispensing/dispensing and compounding licences, in terms of Section 22C.



Overview of submission

- ▶ Definitions
- ▶ Chapter 7: Advisory committees established by the minister
- ▶ Chapter 8: General provisions applicable to the operation of the fund
- ▶ Chapter 9: Complaints and appeals
- ▶ General
- ▶ Proposed amendments to other affected legislation



DEFINITIONS

National Health Insurance Bill (B11-2019)

- Definitions relevant to the profession of pharmacy, the provision of pharmaceutical care, and pharmaceutical services



DEFINITIONS

NHI Bill (B11-2019)

Comment

Health care service provider is defined as:

a “natural or juristic person in the public or private sector providing health care services in terms of any law”

It is important to note that the SAPC registers and records:

- (i) pharmacists;
- (ii) pharmacy support personal, which includes pharmacist’s assistants in various identified categories;
- (iii) pharmacy owners, who may be natural or juristic persons and includes the State as owners of pharmacies operating in the public sector, as well as private owners; and
- (iv) pharmacy premises, in both the public and the private sector.



DEFINITIONS (cont.)

NHI Bill (B11/2019)	Recommended amendment
<p><i>Health goods</i> read together with <i>health-related products</i> – it is noted that <i>health goods</i> by definition includes, medical equipment, medical devices and <u>supplies</u>. A separate definition is provided for <i>medicine</i>. It is further noted that the definition for <i>health related products</i> begins with the words, “any commodity <u>other than</u> orthodox medicine...”</p>	<p>“Orthodox medicine”</p> <p>(i) not defined in the NHI Bill, trade usage: complementary and traditional medicines (no distinction is made in terms of the <i>Medicines and Related Substances Act</i>, 101 of 1965)</p> <p><u>SAPC recommendation</u>: remove the term “orthodox medicine” from definition</p>



DEFINITIONS (cont.)

NHI Bill (B11-2019)	Recommended amendment
<p>“<i>Health related products</i>” – term used extensively in Section 38 under ‘Office of Health Products Procurement’ – included with medicine and medical devices</p> <p>However!</p> <p>Definition of “<i>health related products</i>” excludes “orthodox” medicines.</p>	<p><u>SAPC recommendation</u>: remove definition from the Bill, replace with “<i>health goods</i>” or “<i>health products</i>” –</p> <ul style="list-style-type: none">• preference for <i>health products</i> (internationally accepted term – (widely used by the World Health Organisation)• In addition, health products should include medicines, vaccines, diagnostics and medical equipment, as such definition would therefore be aligned to the vision of universal health coverage



DEFINITIONS (cont.)

NHI Bill Text (B11/2019)	Recommended amendment
<p><i>Primary health care</i> is defined as “addressing the main health problems in the community through providing promotive, preventative, curative and rehabilitative services, and:</p> <p>(i) Is the first level of contact of individuals, the family and community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process; <u>and</u></p> <p>(ii) in the public health sector is the clinic, and in the private health sector is the general practitioner, primary care nursing professional, primary care dental professional and primary allied health professional, though multi-disciplinary practice”.</p>	<p>pharmacy has been omitted from the definition of primary health care</p> <p><u>Pharmacy is <i>vital</i> to primary health care:</u></p> <p>(i) Pharmacy- more often the first level of contact with a patient, or care giver with the health system</p> <ul style="list-style-type: none">• user is able to access a pharmacy in the private sector without an appointment• the business hours of a pharmacy include week-ends and often extend beyond the traditional working hours = after-hours access• a pharmacist interacts with a user on a more frequent basis (medical practitioner/nurse may only see the user two times a year)



DEFINITIONS (cont.)

NHI Bill Text (B11/2019)	Recommended amendment
<p><i>Primary health care</i> is defined as “addressing the main health problems in the community through providing promotive, preventative, curative and rehabilitative services, and:</p> <p>(i) Is the first level of contact of individuals, the family and community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process; <u>and</u></p> <p>(ii) in the public health sector is the clinic, and in the private health sector is the general practitioner, primary care nursing professional, primary care dental professional and primary allied health professional, though multi-disciplinary practice”.</p> <p>(This definition <u>excludes</u> pharmacy)</p>	<p><u>SAPC Recommendation</u>: insert “pharmacist” and “Primary Care Drug Therapy (PCDT) pharmacist” in (ii).</p> <p><u>Pharmacy is <i>vital</i> to primary health care:</u></p> <p>(i) Pharmacy – more often the first level of contact with a patient, or care giver with the health system</p> <ul style="list-style-type: none">• user is able to access a pharmacy without an appointment.• the business hours of a pharmacy include week-ends and often extend beyond the traditional working hours = after-hours access• a pharmacist interacts with a user/patient on a more frequent basis• Pharmacies also provide screening and testing, peak flow measurement, reproductive health services, administration of an intra-muscular or sub-cutaneous injection, administration of immunisation and primary care drug therapy.



DEFINITIONS (cont.)

Further:

pharmacy must be included in the definition of *primary health care* because:

The SAPC, as a statutory health council, allows for and encourages multi-disciplinary health services within a pharmacy, e.g.:

- employing nursing practitioners in the pharmacy clinics
- using electronic general practitioner telemedicine systems



DEFINITIONS (Concl.)

(a) The definition of *primary health care* must be amended to read as follows:

“Primary health care means addressing the main health problems in the community through providing promotive, preventative, curative and rehabilitative services, and:

(i) is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination”; and

(ii) in the public health sector is the clinic **and pharmacy**, and in the private health sector is the general practitioner, primary care nursing professional, primary care dental professional, **the pharmacist, the Primary Care Drug Therapy (PCDT) pharmacist**, and primary allied health professional, though multi-disciplinary practice.



SECTION 5 (7): Registration as users

NHI Bill Text (B11/2019)	Recommended amendment
<p>Section 5(7) states that “<u>Unaccredited</u> health establishments whose particulars are published by the Minister in the <i>Gazette</i> must, on behalf of the Fund, maintain a register of all users containing such details as may be prescribed”.</p>	<p><u>SAPC Recommendation</u>: This appears to be a typo. We recommend that Section 5(7) should read as follows: “<u>Accredited</u> health establishments whose particulars are published by the Minister in the <i>Gazette</i> must, on behalf of the Fund, maintain a register of all users containing such details as may be prescribed”.</p>



SECTION 11: Powers of Fund

NHI Bill Text (B11/2019)	Recommended amendment
<p>Section 11(i)(vi) provides for the fund to <i>identify, develop, promote and facilitate the implementation of best practices in respect of:</i> ... “fraud prevention within the Fund and within the national health system”</p>	<p><u>SAPC Recommendation:</u> In terms of Section 11(i)(vi), the SAPC recommends the inclusion of the following:</p> <p>... “fraud prevention, <u>waste and abuse</u> within the Fund and within the national health system”</p> <p><i>This, in order to ensure that abuse and wastage of resource that may not stem from fraud is also avoided.</i></p>



CHAPTER 7 - ADVISORY COMMITTEES ESTABLISHED BY THE MINISTER



CHAPTER 7 - ADVISORY COMMITTEES ESTABLISHED BY THE MINISTER

- ▶ The SAPC welcomes and supports the inclusion of persons on such committees, as detailed in Chapter 7, based on expertise in medicine. The SAPC trusts that such expertise does in fact include experts in pharmacy.
- ▶ In this regard, the SAPC assumes that “medicine” as it is included herein pertains to the definition of medicine as provided in the Bill.
- ▶ In addition, it should be noted that a pharmacist is an expert in medicine, as their qualification of a Bachelor of Pharmacy includes five core modules named pharmacology, pharmaceutical chemistry, pharmaceuticals, clinical- and social pharmacy which constitute around 70% of the total curriculum.
- ▶ Pharmacists are trained on the holistic approach to medicine, from molecular development to medicines’ impact on a patient’s health.
- ▶ Further, the SAPC looks forward to contributing to such Advisory Committee provided for in Section 27.



CHAPTER 8 - GENERAL PROVISIONS APPLICABLE TO THE OPERATION OF THE FUND

- Section 38: Office of Health Products Procurement
- Section 39: Accreditation of services providers



Section 38: Office of Health Products Procurement

NHI Bill Text (B11/2019)

- Section 38, under the title “Office of Health Products Procurement” opens with the statement that the Board must establish an Office of Health Products Procurement which sets the parameters for the public procurement of **health related products**, and in Section 38(2) it goes on to qualify, stating the procurement of health related products, including but not limited to **medicines, medical devices and equipment**. *However, this is contradiction to the definition of health related products, which expressly excludes “orthodox medicine”.*
- In addition, the definition of health goods expressly includes medical equipment, medical devices and supplies. The use of terminology is further confusing as a different undefined term of health products is then used within Section 38. Section 38(3)(a) relates to the selection of health related products, Section 38(3)(b) requires the development of a national health products list (undefined, and one has to question whether it means health goods), and Section 38(3)(c) mentions the supply chain management of **health related products** mentioned in (b), despite the fact that Section 38(3)(b) uses the term **health products**.



Section 38: Office of Health Products Procurement (Cont.)

Recommended amendment

SAPC Recommendation: (a) There is a need to revisit the definitions of *health goods* and *health related products* and their use throughout the NHI Bill, especially Section 38 which is where the definitions are most critically used. Once again, the SAPC moves for the recommendation that the definition of **health related products be removed from the Bill**, and that it be replaced with *health goods* or *health products*, with the preference for health products as this is the internationally accepted term as used and defined by the WHO.



Section 38: Office of Health Products Procurement (Concl.)

Recommended amendment

SAPC Recommendation: (b) In terms of Section 38(3)(d), the current wording provides for the Office of Health Products Procurement to “*facilitate the cost effective, equitable and appropriate public procurement of health related products on behalf of users*”.

It is recommended that the WHO definition for “promoting affordable and fair pricing and effective financing” which states “equitable access to essential, high-quality and affordable essential medicines and other medical technologies depends on affordable and fair pricing and effective financing schemes”, be used as in line with international benchmarking, including the words “cost effective”, and to sure that the health products procured address not only cost, but also quality and effectiveness.



Section 39: Accreditation of services providers

Section 39, under the title “Accreditation of services providers”, in particular Section 39(2)(b), states that service providers must comply with the prescribed specific performance criteria, which includes *inter alia* the minimum required range of personal health care services and allocation of the appropriate number and mix of health care professionals.

Although no mention is specifically made of primary health care, but rather a broad mention of a minimum required range of personal health care service, **the SAPC wishes to express concern that the absence of pharmacy under the definition of primary health care could limit, if not exclude pharmaceutical services being provided by pharmacies.** This is further highlighted by prevailing legislation under the Health Professions Act and the Allied Health Professions Act which limits multi-disciplinary health care practices. In such cases **the prevailing definition could encourage medical practitioners and nursing professionals to “scope creep” with add-on scopes of practice like dispensing with dispensing licences under Section 22C of the Medicines and Related Substances Act,** instead of including pharmacists to provide pharmaceutical services.



Section 39: Accreditation of services providers (Cont.)

This is further highlighted by Section 37 under the title “Contracting Unit for Primary Health Care”, which by definition would exclude pharmacy from the contracting for primary health care services. Another example of potential exclusion for pharmacy is contained in Section 41, under the title “Payment of health care service providers”, and in particular Section 41(3)(a), following on from Section 37, where it states that only accredited primary health care service providers must be contracted and remunerated by a Contracting Unit for Primary Health Care.



Section 39: Accreditation of services providers (cont.)

(b) It should also be noted that Section 39 address the issue of “needs” of the user. The SAPC has potentially identified that Section 39 addresses the issue of a certificate of need as detailed in the National Health Act. In this regard it must be highlighted that Section 22 of the Pharmacy Act, read together with the Regulations pertaining to the ownership and licensing of pharmacies (GNR.553 published on 25 April 2003), requires that applicants for a pharmacy licence must provide evidence to the Director General: Health that there is a need for pharmaceutical services in the district/area where the owner wishes to establish a pharmacy. In addition, such applicant must also identify what other healthcare services are available in the surrounding area. Added to this is the fact that the SAPC allows and inspects mobile pharmacy units, that operate from a licenced and recorded pharmacy.



Section 39: Accreditation of services providers (cont.)

In terms of Section 39(2)(a) in order for a health care service provider or health establishment to be accredited, they must be in possession of and provide proof of certification by the Office of Health Standards Compliance. The SAPC, in conjunction with the Director General: Health, licenses and records pharmacy premises, thus providing the standard setting of pharmacy premises wherein and from where pharmaceutical services are provided. This regulatory function stretches across all sectors of pharmacy including manufacturing, wholesaling/distribution, consultant, institutional and community pharmacies in both the public and private sectors. In addition, the SAPC has established a permanent inspectorate that not only enables the SAPC to investigate complaints but more effectively enables routine monitoring of all pharmacies licenced and recorded with the SAPC.

The SAPC has also been able to work with and assist the Office of Health Standards Compliance in respect of pharmacies and facilities that provide pharmaceutical services. It is also against this background that the SAPC wishes to recommend caution to the Minister in terms of duplicating functions by the proposed National Health Insurance Fund, the Health Management Offices and the Contracting Unit for Primary Health Care, in the accreditation of service providers and the potential investigation of complaints.



Section 39: Accreditation of services providers (Concl.)

In terms of Section 39(2)(b), the SAPC wish to highlight that a large number of the community pharmacies have clinics within the pharmacy, which clinics have nurses in the employ of the pharmacy. In addition, the SAPC has approved the emerging trend of using technology to bring medical practitioners and patients together in a virtual consultation environment, referred to as “tele-medicine”.



CHAPTER 9 – COMPLAINTS AND APPEALS

- Section 44 – Payment of health care service providers
- Section 46 – Secretariat
- Section 47 – Procedure and remuneration



CHAPTER 9 – COMPLAINTS AND APPEALS

- Section 44(1)(a) which reads “one member appointed on account of his or her knowledge of the law, who must also be the chairperson of the [Board]”, should have the word “Board” replaced with “Appeal Tribunal”.
- Section 46 which reads “The Chief Executive Officer of the [Board] must delegate a staff member of the Fund to act as secretary to the Appeal Tribunal and the Fund must keep the minutes and all records of a decision of the [Board] for a period of three years after the decision has been recorded”, should have the word “Board” replaced with “Fund” and the second mention of the word “Board” replaced with “Appeal Tribunal”.
- Section 47(3) provides that the Appeal Tribunal must determine the outcome of the appeal within 180 days. The SAPC is of the opinion that 180 days is somewhat excessive, given the nature of the business of the Fund, in terms of the fact that the appeal may be by a user who requires health services under the Bill in an emergency, or the delay in paying a health care provider, or refusing accreditation to a health care provider that may delay the provision of health care services. The SAPC is of the opinion that an appeal should where possible be concluded within 90 days.



GENERAL



General comments

- The SAPC notes that throughout the Bill *time frames* are referred to as *timeous* or *within a reasonable time*. **The SAPC recommends that, for efficiency and accountability, specific time frames should be provided where possible.**
- The SAPC notes that, as a result of the provisions of the Bill, amendments of other legislation may be required. **The SAPC notes such amendments and shall keep a noting brief on such amendments in order to determine whether such amendments impact on the functioning of the SAPC and its legislation.**



**Possible amendments to other
legislation:**
*Medicines and Related Substances Act,
101 of 1965*



(b) Section 22A(14)(b) of the Medicines and Related Substances Act, 101 of 1965 be amended to read:

*“No nurse, **pharmacist** or a person registered under the Health Professions Act, 1974, or similar Act, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned.”*



(c) Section 22A(17)(a) of the Medicines and Related Substances Act, 101 of 1965 be amended to read:

(a) *“**authorised prescriber**” means a medical practitioner, dentist, veterinarian, practitioner, nurse, pharmacist or other person registered under the Health Professions Act, 1974”*



THANK YOU

