SOUTH AFRICAN PHARMACY COUNCIL COMMENTS TO THE NATIONAL HEALTH INSURANCE BILL [B11-2019]

The South African Pharmacy Council (SAPC) wishes to take this opportunity to congratulate the Honourable Minister of Health on the publication of the National Health Insurance Bill, B11-2019 (NHI Bill). In this regard the SAPC wishes to express its support towards achieving the envisaged realisation of the right of access to quality personal health care services, and the achievement of universal health coverage.

The SAPC would therefore wish to extend to the Minister any assistance, expertise and skills that the SAPC may have, in ensuring that all pharmaceutical services, pharmacy health care services and pharmacy health care providers are of the highest possible standards as required in order to fulfil the purpose of the NHI Bill.

In terms of Section 3 of the Pharmacy Act, 53 of 1974, the objects of the SAPC include *inter alia*:

(a) to assist in the promotion of health of the population of the Republic;
(b) **to advise the Minister 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 safe guard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and private sector.

The Mission of the SAPC states:
"*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"*

It is against the background of the objects of the SAPC, that comments are provided to the NHI Bill for consideration.

AD SECTION 1 – DEFINITIONS

Section 1 of the National Health Insurance Bill (NHI Bill) provides comprehensive definitions, of which several of definitions are relevant to the profession of pharmacy, the provision of pharmaceutical care and pharmaceutical services, in terms of the NHI Bill.

(a) *Comprehensive health care services* (added since the NHI Bill – 2018), is defined as "health care services that are managed so as to ensure a continuum of health promotion, disease prevention, diagnosis, treatment and management, rehabilitation and palliative care services across the different levels and sites of care within the health system in accordance with the needs of users."

While no healthcare professionals are listed in the said definition, it would be important to note the scope of practice of a pharmacist contained in Regulation 3 read with Regulation 18 of the *Regulations relating to the practice of pharmacy* (GNR.1158 published on 20 November 2000), which Regulations are attached hereto marked Addendum A.

In this regard, Pharmacists provide comprehensive health care services through the provision of pharmaceutical care, where pharmaceutical care is a **patient-centered**, outcomes-oriented pharmacy practice that requires the pharmacist to work in concert with the **patient** and the **patient's** other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective. The goal of Pharmaceutical Care is to optimise the **patient's health-related quality of life, and achieve positive clinical outcomes, within realistic economic expenditures**.

(b) *Health care service provider* (a new definition added after the NHI Bill 2018), is defined as a "natural or juristic person in the public or private sector providing health care services in terms of any law".

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:

(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.

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 sector, as well as

pharmacies providing pharmaceutical services in both the private and public sector. In addition it should be noted that the SAPC is required in terms of the Medicines and Related Substances Act, 101 of 1965, and in particular Sections 22A and 22C, to assist the Director General, 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.

(c) *Health goods* read together with *health related products* – it is noted that *health goods* by definition includes, medical equipment, medical devices and supplies. A separate definition is provided for *medicine*. It is further noted that the definition for *health related products* begins with the words, "any commodity other than orthodox medicine…"

(i) Orthodox medicine is not defined in the NHI Bill, although in terms of trade usage this may refer to complementary and traditional medicines. However, no such distinction is made in terms of the Medicines and Related Substances Act, 101 of 1965 and therefore the recommendation is to remove such term as orthodox medicine from the NHI Bill.

(ii) It is further noted that the term "*health related products"* is used extensively in Section 38 of the Bill under the title 'Office of Health Products Procurement', wherein it is included with medicine and medical devices, however the definition of *health related products* expressly excludes *inter alia* "orthodox" medicines. Further discussions herein are detailed under the comments specifically pertaining to Section 38. As discussed under Section 38, the SAPC move for the recommendation that the definition of *health related products* be removed from the Bill, and the correct term should be *health goods* or *health products*, with the preference for *health products* as this is the internationally accepted term as used and defined by the World Health Organization (WHO). 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 and the "bigger picture"

(d) *Primary health care* (added since the 2018 NHI Bill) is defined as "addressing the main health problems in the community through providing promotive, preventative, curative and rehabilitative services, and:

(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; and

(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."

It is of grave concern that pharmacy has been omitted from the definition of primary health care, (as pharmacy does not fall within allied health professionals). In respect it is of the utmost importance that cognisance be taken of the vital role pharmacy plays in primary health care:

(i) pharmacy, especially in the private sector is more often the first level of contact with a patient, or care giver etc with the health system. In this regard, it should be noted that a 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, allowing the user to access the pharmacy "after hours", a pharmacist interacts with a user on a more frequent basis, and in the case of chronic medication, this would be monthly, as opposed to the medical practitioner or nurse who may only see the user twice yearly;

(ii) Included in the services provided in pharmacy are blood glucose, blood cholesterol and/or tri-glycerides, urine analysis, blood pressure monitoring, HIV and AIDS pre-test counselling, HIV and AIDS testing and post-test counselling, pregnancy screening, peak flow measurement, reproductive health services, administration of an intra-muscular or sub-cutaneous injection, administration of immunisation and primary care drug therapy pharmacist (PCDT with a permit under Section 22A(15) of the Medicines and Related Substances Act (supra); and

(iii) Aligned to the definition of *health care service provider* (supra), the role of pharmacy in primary health care can best be detailed as:

Promotive/Public Health Services	○ Lifestyle programmes ○ Lifestyle education and modification	▪ Smoking cessation, ▪ Weight control, ▪ Alcohol abstinence, ▪ Substance abuse programmes ▪ eating plans, ▪ exercise, ▪ sleep hygiene; and ▪ stress control

Preventative services	○ Screening for communicable and non-communicable diseases	▪ Blood pressure ▪ Blood glucose and HbA1c ▪ Blood cholesterol (HDL, LDL, VLDL and triglycerides) ▪ Weight, Body Mass Index (BMI) and waist circumference, hip to waist ratio ▪ HIV infection ▪ Group A Strep infection ▪ Tuberculosis (TB) screening
	○ Family planning ○ PrEP and PEP initiation ○ Influenza vaccination ○ Wound care ○ Antimicrobial Stewardship	
	○ Well Baby care	▪ including Expanded Progamme on Immunization (EPI), ▪ baby weighing, and ▪ breast and formula feeding advice
	○ Mental health support ○ Asthma and Chronic Obstructive Airway Disease (COAD) support	▪ including inhaler techniques, ▪ peak flow; and ▪ spirometry
Curative care	○ Dispensing acute and chronic medicine ○ New medicine services ○ Medicine utilisation reviews ○ Medicine adherence programmes ○ Treat to target – point of care testing ○ Primary Care Drug Therapy (PCDT) ○ Adverse event management and reporting ○ INR monitoring	

	○ PIMART – 1st line ART initiation	
Rehabilitative services	○ Ambulatory aids ○ Surgical equipment ○ Unit dose dispensing	
Palliative care	○ Monitoring of pain management plans ○ Total Parental Nutrition (TPN) ○ Incontinence care ○ Stoma care ○ Oxygen services - COAD	

It is further noted that that the definition of *primary health care* is based on the current status quo of the health care system and does not necessarily take into consideration primary health care in the future under the proposed NHI model. It is noted that there is nothing in law that prevents pharmacy taking a first line approach in the public sector primary health care (clinics), where pharmacies/pharmacists can assist patients with Pharmacy Initiated Therapy (PIT) as it successfully practiced in the private sector.

In respect to the exclusion and thus the recommendation that pharmacy be included in the definition of *primary health care* it is further noted that:

(i) The SAPC as a statutory professional health council, almost exclusively allows for and in fact encourages multi-disciplinary health services within a pharmacy, such as employing nurse practitioners in the pharmacy clinics as well as electronic general practitioner telemedicine systems, in contrast to the restrictive legislation under the Health Professions Act and the Allied Health Professions Act; and

(ii) Should it be necessary, the SAPC may consider making oral submissions to the Portfolio Committee: Health with regards to the role played by pharmacists in primary health care and the measures taken by the SAPC to encourage multi-disciplinary health teams.

The exclusion of pharmacy is further compounded when one considers the potential application of Section 39 under the title “Accreditation of service providers”, where the words “details of treatment administered including medicine dispensed and equipment

used…" is listed in Section 39(5)(c). Extensive details highlighting the potential problems associated with the exclusion of pharmacy from the definition of primary health care is provided hereunder in the specific comments related to Chapter 8 of the NHI Bill.

RECOMMENDATIONS:

(a) The definition of *primary health care* to 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."

(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;

AD SECTION 5(7)

Clarification of a potential typing error where Section 5(7) states that "Unaccredited health establishments must maintain a register of all users". Should Section 5(7) not start with the word "An accredited"?

AD SECTION 11

In terms of Section 11(i)(vi), the SAPC recommends the inclusion of the following:
"fraud prevention, waste and abuse within the Fund and within the national health system"

AD CHAPTER 7 - ADVISORY COMMITTEES ESTABLISHED BY THE MINISTER

(a) 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 the expert in medicine, as their qualification of a Bachelor of Pharmacy includes five core modules named pharmacology, pharmaceutical chemistry, pharmaceutics, clinical- and social pharmacy which constitute around 70% of the total curriculum. Pharmacists are thus trained from first year level on the holistic approach to medicine, from molecular development to ultimately impact on patient's health.

(b) Section 27 provides for a Stakeholder Advisory Committee, which includes representatives from the statutory health professions councils. The SAPC looks forward to contributing to such Advisory Committee. The SAPC would like to seek clarity as to the funding of such committee, and states for the record that should such committee be established for purposes of assisting the Fund, then the Fund should fund such committee in order to deliver on its mandate.

AD CHAPTER 8 - GENERAL PROVISIONS APPLICABLE TO THE OPERATION OF THE FUND – SECTION 38

(a) 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 (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.

RECOMMENDATION that –

(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 move for the recommendation that the definition of *health related products* be removed from the Bill, and the correct term should be *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.

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 terminology for *"promoting affordable and fair pricing and effective financing,* be used 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 and to sure that the health products procured address not only cost, but also quality.

AD CHAPTER 8 - GENERAL PROVISIONS APPLICABLE TO THE OPERATION OF THE FUND – SECTION 39

(a) Section 39, under the title "Accreditation of services providers", and 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.

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.

(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.

(c) 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, licences 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.

(d) 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”.

AD CHAPTER 9 – COMPLAINTS AND APPEALS

(a) 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”.

(b) 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”

(c) 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

(a) 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.

(b) The SAPC notes that as a result of the provisions of the Bill may require the amendment of other legislation. 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.

(c) In addition to the specific comments relating to the various sections of the NHI Bill, the SAPC wishes to inform the Minister of pending legislation relating to the Specialist Pharmacist: Public Health Management. The SAPC wishes to highlight the substantial role such a qualified and registered specialist pharmacist could add to the functions of the District Health Management Office (Section 36), the Contracting Unit for Primary Health Care (Section 37) and the Office of Health Products Procurement (Section 38).

CONCLUSION

The SAPC, in support of the NHI initiative by the Minister of Health, wishes to:

(a) express its continued support of universal health coverage;

(b) continue to play an integral role in advising the Minister and other persons on NHI matters as they relate to pharmacy; and

(c) support the inclusion of pharmacy in the national health system.