Pharmaceutical Society of South Africa

Comment on the National Health Insurance White Paper

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1. Introduction

The Pharmaceutical Society of South Africa (PSSA) welcomes the opportunity to comment on the NHI White Paper, as the draft policy document that will, once finalised, guide the policy and legislative framework that should enable universal coverage of healthcare services for all South Africans.

The PSSA attaches hereto its 2011 Submission on the Green Paper, as many of its comments remain valid. The PSSA is disappointed that its recommendations did not find expression in any of the elements of the

NHI as published in December 2015. PSSA recommends that the various elements of the NHI now form the basis of discussions on the practical implementation, and the implications (intended or not) of the proposed policy, and urges that a formal regulatory impact assessment should be undertaken on all elements.

The numbering of paragraphs in the White Paper is welcomed, as it facilitates comment on specific elements. The numbering system works well until the paragraph numbers 327 – 335, initially applied to sections 7.6.3 and 7.7, are unfortunately repeated first in the introduction to chapter 8 and then again in sections 8.1 to 8.3.

2. General Principles

At the outset, the PSSA would like to share the guiding principles that it has determined should underpin all policies affecting the provision of pharmaceutical services.

- It is in the interest of patients, individuals and communities that the pharmacist, where possible, is accountable for the provision of pharmaceutical services including all services in terms of the Pharmacy Act which fall within the scope of a pharmacist.

- Pharmaceutical service provision in an NHI model will be determined on need and informed by burden of disease and community demographics and in this respect flexibility needs to be provided in the frameworks within which a pharmacist can work.

- Provision of pharmaceutical services by an individual in an independently owned facility or a state facility as well as the provision of pharmaceutical and primary healthcare services in a community pharmacy should all be considered as options in contracting pharmaceutical services. Pharmacy Council frameworks will need to be reassessed and aligned to meet these needs.

- Multidisciplinary healthcare practices need to be facilitated taking account of professional skills and capabilities. Risk-taking, fair remuneration and new models must be explored. Roles and responsibilities need to be clearly defined to ensure that adequate services can be provided through the formation of appropriate teams.

- Practice standards determined and enforced by the Pharmacy Council should guide the provision of pharmaceutical services in conjunction with the Office of Health Standards Compliance.

- The nature of pharmaceutical services, as contained in the scope of practice for pharmacists, that can be contracted must be fairly

remunerated and should be guided by the current Pharmacy Council guidelines.

- Patient care should not be compromised as a result of lack of willingness by the NHI fund to provide the type of pharmaceutical care envisaged by the Pharmacy Act.

- Where appropriate, patients and other healthcare providers should have access to pharmaceutical services at an advanced or specialist level including PCDT pharmacists, authorised prescriber pharmacists, clinical pharmacists, pharmacokineticists and industrial pharmacists and possibly other specialist pharmacists as needed.

- The re-engineering of the primary healthcare system focuses on nurse-driven services. The PSSA would like to express concern because revelations at the Private Healthcare Market Inquiry showed that there are no registers of the various categories of nurses showing who they are, where they practise and what their authorised scope of practice is. This needs urgent correction.

- At a meeting with Dr Anban Pillay on 30 May 2016, Dr Pillay confirmed that the White Paper should not be read as dealing with specific matters as its purpose is merely a guidance document and not an implementation prorocol.

3. The Value Proposition of Pharmacy within the NHI

From the outset, the PSSA wishes to confirm the seminal role played by pharmacists in the value chain of the delivery of healthcare. Pharmaceutical services must be provided by persons duly qualified, accredited and experienced, as certified by the Pharmacy Council. **The involvement of the lay (non-pharmacy-trained) person in medicines services should not take place**, not even in the name of shortages of skills or medicines distribution concerns in this field. The possibility for abuse, breaches of quality assurance, risks to patient safety, including the possibility of death or serious and irreversible harm are too large where medicines are concerned to leave in the hands of any lay, or even a partially trained, person.

The contribution of pharmacy includes the list set out below. Sadly pharmacists are often, also in the eyes of those in the health sector, relegated to that of “the professionals who charge dispensing fees on medicines”.

Very few other healthcare professionals are equipped to render the range of services outlined below, with minimal systems, training

and other changes required. Furthermore, pharmacists are unique in actually having implemented multi-disciplinary approaches to the practise of healthcare – many pharmacies employ or house private nurse practitioners, and hospital-based pharmacists form a key part of the professional team.

In particular, the anti-microbial stewardship programme in hospitals, and addressing the significant challenge of inappropriate antibiotic use, requires active involvement of pharmacists.

This role and experience should be harnessed in realising the right of access to healthcare. As was pointed out by the PSSA in its 2011 Green Paper Submission, the scope of the practise of pharmacy is much wider than what is generally believed.[1]

Medicines, and to a certain extent medical devices:[2]

- Manufacturing, importing and quality control of medicines – this ensures that medicines are manufactured to internationally accepted good manufacturing practice (GMP) standards requiring specialised skills and continual training which are monitored by the South African Pharmacy Council and the Medicines Control Council on an on-going basis).
- Warehousing, control and distribution of medicines – necessary to ensure that medicines are stored, controlled and distributed in a manner which maintains the product quality and integrity for the duration of the approved shelf life.
- Provision of effective tracking system for all batches of medicines – to ensure effective recall of medicines that do not conform to set limits thus managing an efficient recall).
- Provision of effective systems to detect and prevent counterfeiting of medicines – to ensure that unregistered, and thus unlawful, medicines are not used by the public while maintaining the integrity and quality of medicines that have been assessed by the Medicines Control Council.
- Adverse Drug Reaction reporting – pharmacists are currently the only healthcare profession required by their statutory council to contribute to this essential review of medicine use.
- Pharmacovigilance – ensures the safe and effective monitoring of effective use and assesses the efficacy of treatment as a whole prescribed to the patient; that is, assessment of all medicines, including those from different prescribers, that are being used by the patient and not merely considering one particular medicine.

Lay persons can, by law and education, not fulfil these functions, all of which are designed to ensure patient safety and medicines quality and efficacy. It is in the interest of patients, individuals and communities that

[1] Including the services listed in the Rules for Services for which pharmacists may levy a fee, BN 193 of 20 December 2010.
[2] The Responsible Pharmacist is accountable to the Pharmacy Council for not complying with the activities as laid down in legislation. In addition, there a separate licence issued by the Medicines Control Council to register and market medicines.

the pharmacist, where possible, is accountable for the provision of pharmaceutical services including all services which fall within the scope of a pharmacist in terms of the Pharmacy Act.

Disease management

- Pharmacotherapy, chronic disease management and improvement of health outcomes
- Clinical interventions and ward rounds
- Pharmacists are experts on pharmaco-dynamics and pharmaco-kinetics.

Managed care and medicines benefit management

- Pharmaco-economic expertise and financial management of medicine expenditure
- Health outcomes measurement – e.g. treatment failures, inappropriate and inefficient treatment can be identified

Training and support

- Training of pharmaceutical support staff and of pharmacists at academic institutions and in-service
- Continuing professional development for doctors, nurses and pharmacy staff

Health promotion and public health programmes

- Patient education
  - When pharmacists dispense medicine to their patients / clients, whether it was prescribed or initiated by the pharmacist, time is spent to explain what each of the medicines are, their intended use, the effect they would have on the patient and recommendations with respect to safely taking the drugs in combination with the patient's other medicine and / or vitamin and food supplements.
  - Patients are often more readily inclined to discuss their ailments and the prescribed treatment with their pharmacist, requesting information that should already have been communicated to them by the prescriber, or that might have been lost in translation. The point is that pharmacists educate their patients in terms they understand and fulfil a vital role in ensuring patient adherence to treatment regimens.
- Pharmacists are key partners in Antimicrobial Stewardship programmes
  - Apart from dispensing healthcare practitioners, pharmacists are the only gatekeepers of medicine and the rational use thereof. Whether in a hospital or outpatient setting, pharmacists are in a unique position to measure antimicrobial prescriptions against the infection their patient is presenting with.
  - Not only is the patient duly informed of the correct way in which he / she is required to take the antibiotic, but also warned against not

finishing his / her antibiotic course and possible resistance as a consequence thereof.
    - Pharmacists are the only healthcare providers who can prospectively intervene in a patient's treatment through either in-person or telephonic conversation with the prescriber, thereby effectively safeguarding their patients against sub-optimal and / or non-rational antibiotic treatments.
    - Behind the scenes, pharmacists play an integral part in decision-making forums that decide what would be best practice within South Africa.
    - Pharmacists actively preserve the antimicrobial arsenal available to us through ensuring that prescribed antimicrobial regimens are followed
- Pharmacists are key partners in rational medicine use evaluation programmes, including. the EML process and the revision of the National Drug Policy, which has been part of the 10-point plan for more than 6 years.
    - Pharmacists are extensively educated in and continuously kept up to date of the latest medicine usage rationales and programmes across all clinical disciplines.
    - Pharmacists also understand the effect different medicines have on one another with respect to efficacy (either sub-therapeutic doses or overdose toxicity) and associated adverse drug interactions.
- For these reasons and many more, pharmacists have been contributing constructively and effectively to South Africa's National Drug Policy and Essential Medicines List and treatment guidelines. In fact, there are quite a few South African pharmacists who play integral roles in the establishment of international best practices within the World Health Organisation and other similar institutions.
- Pharmacists are the most affordable first-line of access to patients outside of the public health system:
    - Within their scope of practice, pharmacists are able to provide immediate treatment for their patients' ailments.
    - Frequently, patients choose to visit their pharmacists instead of their general practitioners or hospitals, as an additional consultation fee is not incurred apart from the cost of the medicine provided.
    - Pharmacists are in a unique position to perform a vital primary healthcare service in the larger healthcare scheme of South Africa, with adequate knowledge to refer patients to healthcare providers higher up in the health value chain.
    - By utilising the extensive network of community pharmacies, both corporate and independently owned, throughout South Africa for basic primary healthcare services, the Department of Health will be able to significantly reduce the patient burden higher up in the health value chain, with the added benefit of satisfied patients having received first-line treatment and/or useful information regarding their disease and where else to seek further medical care with a referral letter in hand.

Primary healthcare

- Health promotion and disease prevention
- Pharmacist initiated therapy
- Primary care drug therapy, which requires an additional accredited qualification based on the Primary Healthcare Standard Treatment Guidelines and Essential Medicines List

Health systems development and coverage

- Electronic system development for South Africa's specific needs
- Private and corporate pharmacies cover the whole of South Africa, especially in rural areas where access to service is restricted

Medico-legal

- Management of and minimisation of medico-legal risks with regards to medicine, medicine interactions and contra-indications

Research and development

- Pharmaceutical research, development and design of products, delivery systems and practice models

The White Paper does not appear to recognise these roles, beyond the possibility of contracting pharmacies into the NHI system as early as the 2017/8 financial year. This however appears to refer only to the logistical skills of pharmacists and not to their clinical skills as healthcare professionals.

The PSSA therefore strongly recommends that the above functions be integrated into the various aspects of the NHI. Pharmacists should not be seen as "yet another provider group", such as GPs to be contracted and managed in the NHI. **Members of the PSSA should be actively involved in all the NHI work streams, and sub-streams may be required insofar as the roles outlined above are concerned.** This involvement should go beyond the mere consultative events taking place and being planned.

4. Comments on selected aspects of the NHI White Paper

4.1 The universal access model

Although it is understood that political decisions have been made in relation to National Health Insurance, as opposed to social health insurance, or mixed models, **the PSSA urge a re-consideration of the necessity of an NHI, to the exclusion of one or more other models, all of which can deliver on the constitutional mandates of access to healthcare, and access to social security**.

Consideration must also be had for the concept that those who are able to afford their own cover, should not be excluded from doing so[3]. Those who can afford it should not increase the burden on the system by contributing to decreased access, or lack of access, to services by those who are unable to afford care. There are already, in the view of the PSSA, too many instances where patients with medical scheme cover are shifted onto the public health system, where they utilise scarce resource[4], including pharmaceutical resources, with associated exacerbations in lack of access and increased waiting times. This also undermines the principles of solidarity, a key component of social security as espoused in section 27 of the Constitution of the RSA, 1996.

4.2 **Centralised procurement and decentralised distribution**

Of specific concern to the PSSA is the suggestion that the distribution of medicines will be through a community-based distribution system. We urge, in the interests of the public, that the distribution of medicines to patients remains as far possible under the control of a pharmacist (par 180).

It is noted (par 232 and 233) that a Central Chronic Medicines Dispensing and Distribution (CCMDD) and Pickup Points (PuPs) are seen as solutions to problems such as public sector stock-outs and an attempt to assist patients to avoid queues for their chronic medicines. The evaluation of these systems, in the absence of a legal framework and/or policy write-up, is difficult. It is noted that these programmes are lauded as having assisted in ensuring increased access to medicines. **PSSA reiterates in this regard a fundamental principle – the correct use of medicine is even more important that just ensuring that the patient gets the medicine.** It seems that the focus is only on the patient getting the medicine, which is wrong. The PSSA is deeply concerned about the implementation of PuPs. PuPs are open to serious abuse and loss, apart from unacceptable handling and issuing of medicines to state patients by unqualified people, not subject to the standards set by the Good Pharmacy Practice (GPP) rules.

The PSSA proposes that in seeking cost effective and efficient methods of creating access by patients to medicines, that further consideration be made to what is in the best interest of patients for the distribution of chronic medicines and to this end request that the profession is involved in the preparation of alternate proposals in conjunction with other stakeholders and role players.

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[3] This concept was included in section 4 of the National Health Act, 2003.

[4] See for example the Supreme Court of Appeal ruling in this regard in the case of *Council for Medical Schemes v Genesis Medical Scheme* (20518/2014) [2015] ZASCA 161; 2016 (1) SA 429 (SCA); [2016] 1 All SA 15 (SCA) (16 November 2015), at para 38 – 44.

The pharmacist in community pharmacy could actually dispense and provide the full service using state stock and there would be no need for central dispensing and distribution except in extreme cases. This would further ensure proper pharmaceutical care where chronic and acute medicines are supplied from the same place and with the pharmacist aware of all medication being taken. Central dispensing and non-pharmacy pick up should thus be limited to areas where there is no pharmacy to deliver the service. This would ensure that the Responsible Pharmacist is indeed actually responsible for the medicines and its distribution to patients, thereby securing patient and medicines quality and safety.

To deliver on the promise of universal access in terms of pharmaceutical services we will need both an enhanced public sector and a strong private sector, where the private sector could, in addition to private patients, also provide a service to public sector patients following an agreed remuneration and service model. **PSSA proposes that discussions on the services and remuneration model be started without delay**. As various pieces of legislation are involved in such discussions, the sooner models are discussed and tested, the better.

According to the NDoH's "Status of NHI Pilot Districts" report of 25 May 2016: "The cost analysis suggests that all four combined CCMDD and PuP tender prices are greater than the average personnel costs associated with the provision of chronic medicines pre-CCMDD."

PSSA, although supporting mechanisms to ensure that patients do receive their medication, is concerned about the issues of legal liability and other concerns on PUPs – if the grocer or postal officer hands over the medicine, the responsibility lies with the dispenser or pharmacist in charge at the point, although there may not be a dispenser or pharmacist physically present. Although it has been said in meetings that the responsibility remains with the pharmacist who dispensed the medicine prior to delivery, this needs to be addressed in the policy.

There are some successes reported as the system alleviated the queues in public sector facilities. However the "Status of NHI Pilot Districts" report goes on to say: "Further arguments in support of keeping collection in facilities relate to the management of parcels that are missing out-of-stock items and to the monitoring of non-adherent patients."

Furthermore, how is compliance with GPP ensured, and how is compliance with section 22A (ito which persons are able to handle which schedules of medicine) secured? Section 22A (16) allows for the possession of medicines only if such person is in possession of a prescription. There are also issues of storage conditions with which pharmacies. Who will be responsible for these at non-pharmacy pick-up points?

What is described as a “pick up” is indeed part of the dispensing of medicines, which, in turn, would require a section 22C dispensing licence. In terms of quality of care, patients would not be able to be informed, or discuss, as is required by the Consumer Protection Act, how they should take their medication, or what specific warnings or risks there may be. They would also not know where, and would probably be unable, to report adverse events, or quality concerns with the medicine. In this, the total health or pharmaceutical care of the patient, which every patient in this country deserves, would be impossible.

In terms of centralised price-setting, as with the reimbursement of contracted-in pharmacy-delivered services, the setting of medicines prices would be an important aspect on which to engage the whole medicines supply industry, sooner rather than later. Any price set by the NHI, and where dispensing fees are linked to such price, would affect logistics providers, wholesalers and retail pharmacists. If de-linked, a process should be include, but not be limited to

- evaluating the cost of rendering the service
- the value of the service
- the legal and professional liability and responsibility (as well as compliance with SAPC, OHSC, etc.) that accompany the service
- addressing issues mooted in the White Paper that relate to the level of reimbursement or remuneration, e.g. performance-based reimbursement, par 336, 348, 350-2
- incentives to ensure availability of services and willingness to contracts, par 344-5, 351, 393 (c)(iii)

It appears very likely that a total overhaul of the medicines supply and pricing system is on the cards, and early engagement would be critical. Linkages of centralised procurement with medicines pricing, health technology assessment (HTA) and possible price negotiations, would be essential to discuss, as it may also relate to the future availability of medicines in South Africa.

The NHI white paper raises concerns over **perverse incentives in connection with the procurement of medicines. The PSSA urges finalisation of the draft documents intended to deal with this issue and at which the PSSA has made extensive comment** (par 374).

4.3 **The purchaser-provider split and multi-disciplinary practices**

The strategic purchasing function, as mentioned in par 321 insofar as purchasing of professional services, such as pharmaceutical and pharmacy-based multidisciplinary services are concerned, merits very careful consideration. By its very definition, a smaller, localised pharmacy will be unable to provide services nationally. This will have a severe impact on rural, underdeveloped and out-lying areas, and exacerbate the closing or downscaling of independent community pharmacies all over the country. **The PSSA opposes centralised buying of pharmacy**

services where it leads to the marginalisation of independent and smaller players.

Multidisciplinary healthcare practices need to be facilitated taking account of professional skills and capabilities, risk-taking and fair remuneration and new models will be explored. Roles and responsibilities need to be clearly defined to ensure that adequate services can be provided through the formation of appropriate teams.

Pharmaceutical service provision in an NHI system will be determined on need and informed by burden of disease and community demographics. In this respect flexibility needs to be provided in the frameworks within which a pharmacist can work. Provision of pharmaceutical services by an individual in an independently owned facility or a state facility as well is the provision of pharmaceutical services in a pharmacy as a primary health care facility, as is the case with community pharmacist should all be options in contracting pharmaceutical services. Pharmacy Council frameworks will need to be reassessed and aligned to meet these needs.

Although larger players may appear to offer economies of scale and ease of contracting, the impact of their designation (very similar to what many PSSA members experience with large medical scheme tenders) as national NHI pharmacy services providers on access to pharmacy services should be carefully scrutinised. The possible effects of this system on competition law, and the need to ensure competition throughout the market should be considered. Single purchaser systems, although instituted by government, could be found to be anti-competitive or decreasing competition in the market. **The PSSA recommends the involvement of the Competition Commission in the NHI proposals**, specifically as it pertains to a single purchaser, centralised procurement and centralised contracting, as well as non-provision of NHI services by entities outside of the NHI.

Where appropriate, patients and other healthcare providers should have access to pharmaceutical services at an advanced or specialist level including PCDT pharmacists, authorised prescriber pharmacists, clinical pharmacists, pharmacokineticists and industrial pharmacists and possible other specialist pharmacists as needed.

4.4 **Coding and reimbursement systems**

The nature of pharmaceutical services that can be contracted, as contained in the scope of practice for pharmacists, must be fairly remunerated and will be guided by the current Pharmacy Council guidelines.

The introduction of ICD-10 coding within the NHI is welcomed. However, there is currently no statutory mandate or obligation on this, and even where there is, e.g. in medical schemes legislation, it is not consistently

applied and the pharmacist relies on codes, if any, provided on a patient's prescription by the prescriber.

In view of the primary healthcare role of pharmacists, it is critical that ICD-10 codes provided at pharmacy level lead to reimbursement of services. Irrespective of the model of reimbursement decided upon, with only capitation and Diagnosis-Related Groups proposed thus far, its application to services rendered in pharmacies is not yet clear.

4.5 **Medical Schemes and the NHI**

Although much has been said on the role of medical schemes, some of which is contradictory, par 401 appears unequivocal in stating that **medical schemes "must only complement (and not duplicate) the NHI service benefits". The exact meaning of this is far from clear**. It is now understood that if hypertension treatment forms part of the NHI, medical schemes' "complementary" benefits would be limited to treatments not funded by the NHI. The challenge in this regard would be to ensure scheme sustainability, even with a risk equalisation mechanism, if only higher-end products and services are to be provided. As an example, if the NHI benefit package requires blood pressure monitoring twice a year, would an NHI-contracted pharmacy not be permitted to offer it more frequently, even if paid out of pocket or if paid by another funding mechanism, such as a medical scheme?

4.6 **Legislative changes and the impact thereof**

Given the dramatic changes that would be necessitated by the NHI in various pieces of legislation (including the Pharmacy Act, and implementation of currently incomplete legal frameworks, such as the Nursing Act and National Health Act), the approach to consultation and engagement should be different. **There should be wide consultation and engagement on these changes early on and not only as part of formal comments to Parliament for example, when it may be far too late to effect technical and practical amendments**. Consultation is only valuable when it includes engagement and interaction with all parties.

For example, all indications are that the Certificate of Need (CON) is to be implemented sooner rather than later, very likely on the recommendation of the Health Market Inquiry Panel. Questions such as which criteria will be applied to pharmacies, the assessment of the viability of pharmacies and the implications should a CON not be awarded or not be renewed, possible limitations of the nature, type and scope of services (as envisaged by section 36 of the National Health Act), should be raised and solved through engagement early on. The link between Health Standards Compliance and the existing GPP standards should also be addressed. Practice standards enforced by the Pharmacy Council will guide the provision of pharmaceutical services in conjunction

with the Office of Health Standards Compliance.

Early engagement and active participation not only ensure greater buy-in and reduce the risk of legal action, it also makes the system in the end practical and implementable.

4.7 Population covered

Disease does not know boundaries such as nationality and refugee status. Persons are already receiving HIV and TB care should be able to access medication when they are able to provide proof that they are resident, i.e. have a fixed address, in South Africa. Should they not received the necessary medicine, it would have an undesirable impact on public health. The same applies to the delivery of babies, and all emergency conditions. Although the White Paper envisages that those lawfully in South Africa will receive coverage by the NHI, the reality may be different.

The impact of this aspect (*de facto* cover to all non-nationals), both in terms of the financing of the system, must be quantified and the level and nature of cover assessed.

4.8 Financing of the NHI

The PSSA also looks forward to the publication of the financing paper of the NHI, and notes that the figures included in the White Paper do not reflect the current and medium-term prospects of the country. **In order to introduce greater certainty into the process, a date for the release of the health financing work should be set**.

The PSSA also urge the NHI teams to consult with, and take note of tax reform proposals made by the Davis Tax Committee (www.taxcom.org.za).

It is acknowledged that sin-taxes and the new sugar tax are already levied, but the PSSA proposes that these taxes, due to the public health burden, should be earmarked for health services.

The complexity of the VAT system, together with the state being the final purchaser of goods and services, requires attention. It must also be clarified whether the mandatory contribution will be deducted before or after payment of PAYE tax.

4.9 Administration of the system

As alluded to above in the value proposition of pharmacy, the adoption of a model whereby **medicines *infrastructure* and medicine *administration* are outsourced to pharmacies (and not just**

medicines provision and delivery) will avoid duplication and create the necessary efficiencies, which is one of the key objectives of the NHI White Paper as per par 59.

4.10 Structures of the NHI

A whole host of bodies, structures and committees are envisaged in the NHI, and others, already in existence, such as the Essential Medicines Committee, are mentioned. Insufficient information is however provided as to the composition, roles, functions and mandates of these structures. **PSSA urges that more details be released on these structures, so as to allow meaningful comment and contributions as to their roles within an NHI**.

- **NHI Benefits Advisory Committe**e (par 130) (as opposed to the **Planning and Benefits Design Unit** – par 326) of the NHI Fund) which is said to have the mandate to "regularly review" the NHI benefits. As their mandate would include assessments of "available evidence on cost-effectiveness", there should be some institutional linkage to the system of HTA envisaged and a link to the OHSC (NHI benefits to be provided at certain standards) is made explicit in par 208.

  Par 135 places the EDL, linked to the "inventory of pharmaceutical, medical supplies and devices" within the ambit of this Committee. They will also be in charge of laboratory benefits (par 141). It is understood that preliminary work for this Committee is being undertaken by the NHI Work Stream on this matter, which will use the existing public sector benefits as its basis, and PSSA again urges the incorporation of public and private sector pharmacists in the early design, and then subsequently in all reviews, of the Benefit Package. Other professionals, such as pathologists, disease entity experts, etc. would also have to be involved. In this regard the establishment of **"Expert Committees"** is welcomed (par 341), and it is proposed that these be set up under the auspices of the Benefits Work Stream at this stage already.

- **Clinic Committees**, which are to be established for all PHC facilities (par 186). These Committees will take charge of "public health campaigns", but further "guidelines" on their composition and work are still to be developed. The PSSA therefore recommends, with reference to its value proposition above, that these developments include pharmacists early-on.

- **District Health Management Offices** (DHMOs) (par 187), one of the key duties of which will be the "purchasing of personal health care services from the function of provision of health services". This means that the decision to contract a pharmacy into a district health system will be left to DHMO. It is not clear how the DHMO's will relate to the

district structures created by the NHA's section 31 on District Health Councils, the authority of local government MEC's in the structure (section 30). Although alignment and local control over budgets, etc. at the smallest unit of the health system is proposed, contracting in services such as those set out above under the value proposition, would then be heavily dependent on a single entity's views on the matter. Obtaining a CON, passing an OHSC inspection, and having rendered administration and services aligned to the NHI may come to naught if no "purchasing decision" is made by the DHMO. The DHMO's relationship with the **NHI Fund's Purchasing Contracting and the Provider Payment Units** and possibly the Performance Monitoring Unit (par 326) is also unclear.

- **National Health Commission** (par 188), aligned to the National Development Plan 2030, is said to be a "collaborative" entity with a focus on "risk factors" of "disease of lifestyle", as well as dealing with "health promotion" and "disease prevention" to reduce the burden of disease and "rising cost of healthcare". This mandate is quite broad, and overlaps with that of the **National Consultative Health Forum**, established in terms of the National Health Act (section 24) and the NHI Fund's Purchasing and Contracting Unit (par 326).

- **Hospital Boards** who will evaluate the minimum competency requirements and CPD for all "health managers" and "health facility managers" (the difference between these two is unclear) (par 210), also with authority over management and staff (par 214), with authority over staff (as opposed to management) is potentially problematic in corporate governance terms. Hospitals will receive delegated authority so as to be so-called "semi-autonomous" (par 211), and they should be "viable units" (par 212). It should be noted that in law delegation and autonomy have technical legal meanings, and are undertaken within the context of the rules of administrative law,[5] and, of course, the SA Constitution. Reference is also made to **Central Hospital Boards** (par 205), with envisaged amendments, but neither the existing mandates or those planned are at this stage clear (par 206 – 207).

- **Clinical Peer Review Committees** (par 342) is proposed to deal with exceptions to the NHI treatment guidelines. In the view of the PSSA, Peer Review goes beyond merely evaluating exceptions to treatment guidelines. It is a system whereby clinical peers to a specific professional (e.g. pharmacists in the case of a specific pharmacist), review the actions of such a professional. This goes beyond the systems exceptions alluded to in par 342. Pharmacy Council and the PSSA already have some oversight over good pharmacy practice, and this should be considered and incorporated into the NHI systems of

[5] See for example the 2013 National Treasury framework in this regard: http://www.treasury.gov.za/legislation/pfma/delegations/Delegation%20Principles%20for%20Financial%20Management.pdf.

peer review.

- The NHI Fund's **Risk Management Committee** (par 383). Although it is understood that the Fund should have risk management systems, including fraud prevention and detection in place, par 383 appears to imply risk management at a health systems level as well. That should be the role of hospital boards, district authorities, etc. as well.

- **Functional Business Units**, referring to the "units of business activity" in Central Hospitals (par 204). Due to its role in Diagnosis-Related Groups and out-patient clinics (par 205), the impact this would have on pharmaceutical planning and supply should be considered.

- No details or descriptions are provided in relation to the various Units of the NHI Fund Units (other than those already alluded to above), e.g. the **Price Determination Unit (of obvious and critical importance to the PSSA, as it assumes a model that significantly differs from the dispensing fee and professional services fee models)**, Accreditation Unit, Procurement Unit and Performance Monitoring Unit. Both the accreditation and performance monitoring functions might have significant overlap with the work of the OHSC and Pharmacy Council

- **Health technology assessment** to inform which health interventions would be provided under the NHI is referred to repeatedly in the White Paper. This pre-supposes some structure or system that will evaluate medicines, medical devices and "other health care interventions" (par 385). It is also referred to in connection with the NHI Benefit Advisory Committee (par 130) as a review structure. No information is however provided as to the structure, nature and extent of the work to be undertaken as part of HTA. HTA in medicines is known to be complex, time-consuming and requiring key decisions to be made on data sets, existing research available, etc. The National Department's own pharmaco-economic guidelines issued in terms of the 2005 Medicines Pricing Regulations remains, to the best of the PSSA's knowledge, unimplemented. **The impact of onerous, local HTA requirements on product pricing, as well as delays in access to interventions, should also be considered**.

5 The NHI Work Streams

The PSSA recommends membership of PSSA members in all the NHI Work Streams, and in particular **Work Stream 2: Design and Implementation of NHI Health Care Service Benefits. This NHI Team should work with the PSSA to ensure pharmacist involvement in clinical interventions and pharmaceuticals**.

Work Stream 2 should **also include the MCC/SAPHRA**, as the body evaluates and grants approval for pharmaceuticals, and on its assessments, medicines will be considered for inclusion in the EML, Benefit Package and for HTA processes. Matters on which the NHI White Paper is silent include the availability of unregistered medicines, i.e. medicines not commercialised or no longer commercialised in SA; clinical trial medicines; and medicines not yet registered but no longer on clinical trial, within the NHI system. Also the role played by pharmacists in research in the health sector, within an NHI system, is not clear, and the involvement of the **National Health Research Council would also be required**.

Work Stream 3: Prepare for the Purchaser-Provider Split and accreditation of providers, would require participation of the South African Pharmacy Council and the Office of Health Standards Compliance. This would ensure that there are no contradictory standards being applied, no overlapping jurisdictions with multiple possible negative effects, and no inconsistencies in outcomes (e.g. if a pharmacy passes an SAPC inspection on the matter of medicines storage, but not an OHSC assessment using the same criteria). Most importantly, basic accreditation by SAPC should be accepted by the NHI. How the Certificate of Need will link into the existing DoH licence, issued under the Pharmacy Act, 1974, should be considered. Legislative change would be required.

Work Stream 3 would also be responsible for contracting with so-called **"multi-disciplinary practices". In pharmacy, this would require finalisation of the private nurse practitioner, prescribing and dispensing nurse legal frameworks under the Nursing Act, as well as the Medicines Act.** The primary care role of pharmacists should be accommodated. Engagement with the HPCSA would also be critical, as HPCSA rules prohibit any other healthcare professional from participating in a multi-disciplinary practice that could be administered by a pharmacy, which already has the systems and infrastructure in place.

Lastly, **PSSA urges that the outcomes and outputs of the Work Streams be made available for public comment**. These outputs are of critical practical importance, and should be tested against both public and professional input.

6 Conclusion

In conclusion, the PSSA reiterates its commitment to universal coverage in healthcare for all. It also confirms its views that:

- The pharmacist should stand central in the rendering of pharmaceutical services, as is envisaged by pharmacy and medicines legislation;

- Pharmacists are able to render a comprehensive service related not only to medicines, but to primary healthcare and health promotion;
- There is serious concerns as to the CCMDD and PUPs;
- Pharmacists who are contracted into the NHI should be compensated fairly;
- Discussions as to the pricing model for medicines should commence urgently;
- Pharmacists should be actively involved in all the NHI Work Streams;
- Details as to the NHI funding and financing is urgently required.

The PSSA looks forward to future engagements with not only Work Stream 3 (on the purchaser provider split), but also other Work Stream 2 (on the benefit package and health technology assessment), as well as Work Stream 6 (on primary care). The work, insofar as it affects pharmacy, should be brought together through a dedicated medicines supply chain group.

Appendix: Scope of practice for pharmacists as per legislation administered by South African pharmacy Council

Pharmacy legislation, under the control of the Pharmacy Council prescribes the scope of practice of the various cadres within pharmacy. This provides a recognised and legislated framework for the contribution that pharmacists can make to healthcare in South Africa. The Pharmacy Act identifies the acts pertaining to a pharmacist as follows;

- the provision of pharmaceutical care by taking responsibility for the patient's medicine-related needs including;
    - evaluation of the patient's medicine related needs
    - dispensing of any medicine or schedule substance on the prescription of a person authorised to prescribed medicine furnishing information and advice with regard to the use of a medicine and determining patient compliance therapy and follow to ensure that patient's medicine related needs are being met
    - the provision of pharmacist initiated therapy
- the compound or manipulation preparation or packaging of any medicine or schedule substance or the supervision there of
- the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, re-packaging, supplying or selling of any medicine or schedule substance or the supervision there are
- the application for the registration of a medicine in accordance with the medicines act.

Further detail is provided under section 1.5.2, the scope of practice of the pharmacist where the following acts are also identified;

- the formulation of any medicine for the purposes of purpose of registration
- the distribution of any medicine or schedule substance
- the re-packaging of medicines
- the initiation and conducting a pharmaceutical research and development
- the promotion of public health

Standards are laid out by the Pharmacy Council for the premises from which a pharmacist provides a service and also for the individual services in the Good Pharmacy Practice Guidelines (GPP) and the standards controlled and monitored by the Council.

In addition, the Pharmacy Council Board notice, number 33 of 2012, published rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees. The services which are covered in these fees are extensive and, the involvement of pharmacists in these services can contribute significantly to improving health care in South Africa. These services include;-

- Compounding
- Dispensing
- Therapeutic medicine monitoring
- Provision of information concerning the medicines
- Blood glucose monitoring
- Cholesterol and triglyceride monitoring
- Blood pressure monitoring
- Urine analysis
- HIV and AIDS pre-test counselling and testing
- Pregnancy screening
- Peak flow measurements
- Administration of an injection
- Administration of immunisation
- Reproductive health service including emergency post coital contraception consultation and family planning
- Pharmacokinetics consultation for specialist pharmacokinetics pharmacists
- Pharmacist initiated therapy and primary care drug therapy medicines use review
- Callout services
- Medicines delivery services
- After hour services