Optimising Emergency Procurement, Cost Benefit Analysis and Pooled Procurement Option

Assessing the legal, policy, budgetary and operational requirements for effective participation in the pooled procurement mechanism

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Executive Summary

This report examines health procurement in South Africa, with a focus on the country's potential participation in a pooled procurement mechanism. It aims to establish a foundational understanding of the current health procurement landscape, covering legal, policy, and operational requirements. The findings will inform further engagements by the government and its stakeholders as they consider participation in a pooled procurement mechanism.

The report is structured into six sections. Following an introduction to pooled procurement approaches, Section 2 provides context of South Africa's health procurement landscape, identifying legal, regulatory, and governance framework governing procurement. Section 3 summarizes the status of South Africa's and the region's health manufacturing capabilities, exploring their alignment with pooled procurement mechanisms. Section 4 offers an overview of existing regional mechanisms, mainly African Pooled Procurement Mechanism (APPM) and the Southern African Development Community (SADC) Procurement Mechanism. Section 5 outlines the barriers, opportunities, and implications for South Africa's participation in pooled procurement mechanisms. Finally, Section 6 sets out recommendations and actions required across different departments.

A review of South Africa's legal framework for health procurement revealed a complex and fragmented landscape, characterized by numerous legislative pieces and policies, which creates both opportunities and potential barriers for participation in regional pooled procurement. Below is a summary of our findings:

- South Africa's public procurement framework has been substantially modernised through the Public Procurement Act (2024) and the NHI Act (2023), creating a more favourable foundation for pooled procurement than existed previously. However, critical legal ambiguities, particularly on the interface between the NHI Act (2023) and the PPA (2024), must be resolved before meaningful regional engagement can proceed.
- Three distinct levels of intervention are required for effective cross-border procurement: system-level (resolving domestic legal and institutional gaps), regional-level (engaging APPM and SPPS governance on favourable terms), and operational-level (aligning data systems, regulatory standards, and supply chain logistics). No single level can be addressed in isolation.
- South Africa's pharmaceutical manufacturing base, the largest in Southern Africa, faces structural challenges including high production costs and limited API manufacturing. Regional pooled procurement offers market expansion opportunities but requires a reconciliation of domestic preference policies with regional open competition requirements.
- Five departments/units bear primary responsibility for South Africa's readiness for cross-border procurement: National Department of Health (lead procurement entity), National Treasury (systemic enabler), Department of Trade, Industry and Competition (industrial policy alignment), South African Health Products Regulatory Authority (regulatory harmonisation), and Department of Science, Technology and Innovation (data systems integration). Implementation requires coordinated, simultaneous action across all five departments.

Participation in regional pooled procurement mechanisms requires alignment with regional legal frameworks. While the pooled procurement mechanisms present opportunities to improve access, supply security, and regional market integration, implementation will depend on clearly defined institutional responsibilities and interdepartmental coordination. The recommendations below therefore outline the priority actions required from the departments and entities bearing primary responsibility for implementation.

- The National Department of Health (NDoH) is expected to lead implementation by identifying and publishing a priority product list for pooled procurement based primarily on access and supply security considerations rather than cost containment alone. To accelerate operational readiness, the should consider immediate establishment of an interim Health Products

Procurement Unit (HPPU) within the Affordable Medicines Directorate, allowing South Africa to begin regional procurement engagement ahead of the full rollout of National Health Insurance (NHI).

- The National Treasury will play a central role in establishing the governance and procurement architecture required for implementation. This includes jointly issuing regulations with the NDoH to define the legal mandate of the HPPU and clarify institutional responsibilities in relation to the Public Procurement Office. The Treasury is also expected to support the alignment of domestic procurement policy through a product-category approach that differentiates between health products protected for domestic industrial development and those opened to regional competition.

- The Department of Trade, Industry and Competition (DTIC) is responsible for balancing regional procurement participation with domestic industrial policy objectives. The DTIC, together with the National Treasury, should define which health product categories should remain protected under domestic preference policies and which categories should be eligible for regional procurement competition. In addition, DTIC should negotiate emergency procurement exemptions within regional agreements to preserve South Africa's ability to respond independently during national emergencies or declared disasters.

- The South African Health Products Regulatory Authority (SAHPRA) is expected to implement regulatory reforms that facilitate cross-border procurement and market participation. This includes reviewing the authorized resident representative requirement, which currently limits supplier participation, and introducing an expedited registration pathway for priority pooled procurement products, including recognition of WHO prequalification mechanisms.

- Finally, the Department of Science, Technology and Innovation (DSTI) is required to support domestic health manufacturers to innovate and compete regionally. This involves funding research and development for formulation improvements, supporting technology upgrades for manufacturing compliance, and facilitating technology transfers for Active Pharmaceutical Ingredients. The DSTI must also lead the implementation of an integrated data system connecting domestic entities with regional platforms. This system will enable real-time data sharing among the NDoH, Treasury, and SAHPRA, while also interfacing with regional digital platforms to support multi-year demand planning and contract management.

Collectively, these recommendations provide a phased and institutionally coordinated pathway for implementing pooled health procurement in South Africa while balancing public health objectives, regional integration, industrial development, and regulatory efficiency.

1 | Introduction

KEY MESSAGES

- **Pooled procurement operates at both inter-country and intra-country levels. Procurement arrangements may be structured across countries or within a single national system, depending on the objectives and scale of collaboration**. At the inter-country level, procurement is coordinated regionally or globally to aggregate demand across participating countries, thereby increasing purchasing power and improving negotiating leverage for critical commodities. At the intra-country level, pooled procurement involves the consolidation of demand among sub-national entities such as provinces, districts, municipalities, or public institutions. This approach is intended to reduce fragmentation, improve coordination, and enhance efficiency within national procurement systems.

- **Inter-country pooled procurement mechanisms can be structured across four models that differ according to the degree of cooperation among participating countries.** These models range from low levels of cooperation, such as information-sharing arrangements, to highly centralized procurement systems. South Africa's participation in any pooled procurement mechanism will therefore depend on the extent to which any model proposed for adoption aligns with national procurement priorities, and the level of authority the country is prepared to delegate to regional or centralized procurement structures.

- **Pooled procurement provides significant efficiencies but also introduces operational and governance challenges.** Aggregating demand through pooled procurement can reduce procurement and administrative costs, generate economies of scale, strengthen bargaining power, and improve supply chain predictability for buyers. Vendors may also benefit from access to larger and more stable markets, reducing transaction complexity and improving planning certainty. However, these arrangements may require participating entities to compromise on procurement autonomy, including flexibility in supplier selection, technical specifications, and procurement timelines. Centralized procurement structures may also create increased dependency risks, particularly where governance weaknesses, delays, or supply disruptions affect the entire pooled mechanism.

- **South Africa has adopted intra-country pooled procurement while considering engaging with regional and continental procurement initiatives.** Within South Africa, pooled procurement is already used for the procurement of essential medicines through nationally coordinated contracting mechanisms aimed at improving affordability, standardization, and medicine availability across the public health sector. In parallel, South Africa is exploring participation in regional procurement initiatives such as the African Pooled Procurement Mechanism (APPM) and the Southern African Development Community (SADC) Procurement Mechanism. These initiatives seek to strengthen regional and continental collaboration, improve market leverage, and enhance supply security for participating countries.

Public procurement involves the acquisition of goods and services from suppliers from local and international markets while adhering to the general principles of fairness, equitability, transparency, competitiveness and cost-effectiveness. Public procurement is regarded as one of the government's most effective means to address the needs of the population that ensures that both goods and services are delivered, while also ensuring value for money is realised (Komakech, 2016). Pooled procurement[1], on the other hand is a collaborative initiative that brings together two or more purchasing authorities or a third-party institution that procures on behalf of its members. This collaboration is characterised by a high degree of interdependence, formalised management practices and a framework for collective action between purchasing entities; and can create monopsony[2] since the power of the buyers is facilitated by the aggregation of their combined knowledge, harmonisation of approach, and consequent collective demand (Barton *et al.,* 2022; Parmaksiz *et al*., 2023).

Pooled procurement aggregates financial and other resources of purchasing entities to improve efficiency and create greater purchasing power. Effective participation necessitates that purchasing

[1] Also referred to as joint, bulk, group, centralized, cooperative or collaborative procurement.

[2] Monopsony is an economic condition where market dynamics are driven by major buyers (opposite of monopoly).

institutions (or countries) maintain reliable demand projections and secure sustained financial resources (Immunisation Economics 2017; WHO 2021). Adherence to harmonised regulatory frameworks, legal requirements and financing processes of the participating purchasing authorities is thus crucial. The Global Fund (2023) views pooled procurement as a mechanism for advancing equitable access to quality health supplies and equipment.

Pooled procurement can operate at two distinct levels: inter-country or intra-country. Inter-country involves aggregation of demand across multiple countries, either regionally or globally. Conversely, intra-country focuses on pooling within the country, where sub national units (counties, provinces, districts) collaborate to consolidate their demand. In countries with devolved healthcare systems, intra-country pooled procurement between the different governance units can positively enhance the availability and affordability of healthcare services and products by leveraging on coordinated joint-resource allocation (Barton *et al*., 2022). When implemented at regional or global level, pooled procurement often promotes equitable access of quality-assured health products across the participating nations (PAHO, 2022).

The benefits and drawbacks of pooled procurement, however, differ when viewed from both the buyer's and vendor's perspectives. Table 1 below summarizes these perspectives.

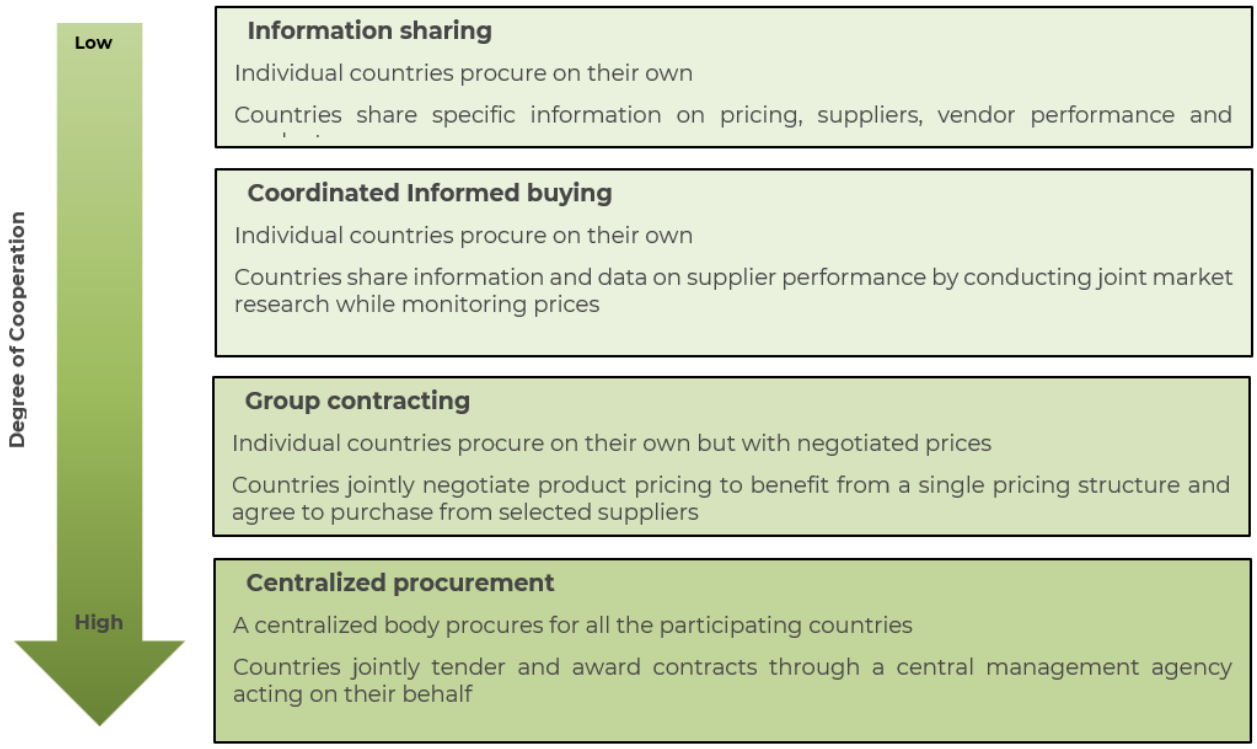
Table 1: Opportunities and limitations of pooled procurement

	Buyers	Vendors
Opportunities	**Cost savings -** Benefit from reduced prices leading to more affordable supplies	**Expanded market access -** Gain increased sales revenue to previously "out of reach" customers
	Efficiency - Lower administrative burden in supply chain management (although there is a greater need for centralised coordination)	**Improved market visibility & forecasting** - Improved forecast availability and accuracy, enabling more efficient production planning
	Access and quality assurance - Enhanced access to commodities where new bidders participate based on aggregated quantities whilst reducing the risk of supply shortages or stockouts that can disrupt health service delivery.	**Streamlined operations -** Reduced number of procurement processes and standardisation
Limitations	**Compromise on autonomy - Buyers** across the countries (or sub national units) must be willing to accept agreed standardisation of goods and services and overriding of vested interests, which without political goodwill might be challenging, especially where there are differing or competing interests	**Competition & price pressure -** Can lead to reduced unit prices and possible revenue decline due to increased competition
	Slower decision-making - Collaborative processes often involve consensus-building, which can lead to longer decision cycles compared to independent purchasing	**Increased dependency risk -** Greater reliance on a few large collective buyers can concentrate business risk, making the vendor vulnerable if a major contract is lost

Source : SADC 2012, Barton et al., 2022.

The degree of coordination within inter-country ranges from low to high, and different activities, procurement processes and the organisational arrangements involved. The United Nations Economic Commission for Africa (2023) classifies this coordination into four models as shown in Figure 1 below. The extent to which countries utilise these models depends on, and is often influenced by, regionally agreed laws, policies, processes and governances, as this facilitates coordination for countries to jointly procure.

Figure 1: Models of inter-country pooled procurement



Source: Adapted from Abudu & Ayele (2024); UNECA 2023; and Espin et al., (2016)

Following improvements in the public procurement systems over the last three decades, there are now opportunities to explore joining regional pooled procurement mechanisms, in particular the African Pooled Procurement Mechanism and the SADC Procurement Mechanism. This report will examine the legal framework and potential obstacles to participation in pooled procurement. It is important to note that these mechanisms represent a higher degree of cooperation, as illustrated in Figure 1, and thus the requirements for participation have been the focus of this review.

2 | Health Procurement Landscape in South Africa

KEY MESSAGES

- **South Africa's public procurement regulatory framework is highly fragmented but is progressively shifting towards centralisation.** Since the 1995 reforms aimed at addressing socio-economic disparities, procurement has been guided by numerous, fragmented legislative pieces and policies, though newer initiatives like the Procurement Act (2024) and the National Health Insurance (NHI) Act (2023) seek to streamline operations, reduce fragmentation, and support strategic bulk purchasing.
- **Procurement activities are distributed across national, provincial, and district government levels to balance economies of scale with localised decision-making**. The National Department of Health coordinates large, centralised tenders to secure cost-effective national contracts, while provincial departments manage regional purchasing, warehousing, and distribution, and district offices operate under delegated procurement systems with strict financial caps.
- **There is no specialised regulatory framework exclusively for health procurement, forcing institutions to rely on general public procurement laws**. The acquisition of medical supplies and services must navigate a complex web of general statutory provisions, such as the Constitution, the Public Finance Management Act (PFMA), alongside policies like the Preferential Procurement Policy Framework Act.
- **Domestic socio-economic policies, particularly those mandating preferential treatment and local content, pose significant barriers to joining regional pooled procurement mechanisms.** Current and upcoming legislation obligates procuring entities to reserve bids for historically disadvantaged groups and meet local production thresholds, which fundamentally clashes with regional or international agreements that typically require uniform supplier eligibility and cannot limit participation strictly to domestic suppliers.
- **Existing legislation contains critical ambiguities that complicate participation in international or cross-border procurement agreements.** There are significant legal and operational gaps, such as the PFMA lacking explicit provisions for internationally sourced contracts, an unclear scope and definition of responsibilities for the newly established Health Products Procurement Unit (HPPU), and uncertainty regarding how state-owned enterprises can participate fairly in regional bids.
- **Operational and governance deficits, such as the absence of a centralised invoicing system and strict budgeting constraints, threaten successful regional integration.** South Africa's challenges in comprehensively tracking the total value of processed invoices at a national level increases the risk of late payments that could disrupt regional supply chains, while strict domestic rules requiring guaranteed budget availability prior to issuing tenders may conflict with the synchronised timelines of a regional procurement mechanism.

While South Africa currently engages in a form of intra-country pooled procurement, particularly at the national level for essential medicines, there is now a growing interest in exploring opportunities for participation in a regional pooled procurement mechanism. This section outlines the existing health related procurement activities at different levels of government and details the regulatory framework governing public procurements. This will provide a basis for assessing the feasibility and implications of joining a regional pooled procurement mechanism, which shall be explored in subsequent sections of the report.

2.1 Introduction to the health procurement landscape

Public procurement reforms in South Africa started in 1995 and focused on two broad areas, the promotion of the principles of good governance and the introduction of a preferential system to address

socio-economic objectives aimed at historically disadvantaged groups (Ambe *et al*., 2012). The redesign of the public procurement system stemmed from the recommendations of the Task Force's report[3] which recommended greater involvement from small, medium and micro enterprises (SMMEs) owned by historically disadvantaged groups (World Bank, 2003). These recommendations were embraced in the Constitution (1996) and subsequent legislation. Since then, the policy and legal landscape for procurement have evolved and become fragmented, with various legislative pieces, acts, regulations, and policies guiding public procurement, as summarised in Table 2. The new Procurement Act (2024), once fully enacted, will address some of the fragmentation which should simplify the procurement legislative framework and support alignment where existing ambiguity exists between different pieces of legislation. However, at present, the existing legislation remains in force and as such, both the existing legislation and the new Public Procurement Act are described in further detail within this section.

Over the past decade, there has been a growing shift to centralise procurement, which increases the ability to pool procurement across government departments. The Office of the Chief Procurement Officer (OCPO), established in 2013, was centrally responsible for the public procurement regulatory framework and policies; and within its structure managed contracts on behalf of multiple government institutions and oversaw the design and establishment of the strategic procurement regulatory environment. More recently, the Procurement Act (2024) once fully enacted will formally establish the Public Procurement Office (PPO) within the National Treasury, which among other functions, will enforce procurement standards - key in advancing the use of the pooled procurement by consolidating bulk purchasing across government institutions, aiming to leverage economies of scale and reduce costs. In addition, the establishment of a Health Products Procurement Unit within the National Health Insurance Fund under Section 38 in the National Health Insurance (NHI) Act (2023) allows for strategic purchasing of healthcare services, medicines, and related goods from accredited providers, utilising standardised specification. A comprehensive review of the regulatory framework of public procurement is discussed in detail under section 2.3. However, as we explore in later sections of this report, there is currently ambiguity over precise roles and responsibilities when considering health related procurement.

Table 2: Summary of the laws, policies and institutions that regulate procurement, 1995-2025

Acts, Policies or Institutions	What it addresses with respect to procurement
The Constitution of the Republic of South Africa, 1996	Section 217 of the Act establishes the primary and broad secondary procurement objectives.
Green Paper on Public Sector Procurement Reform, 1997	Recognised that public sector procurement can be a government tool to achieve economic goals, including socio-economic objectives.
Public Finance Management Act (PFMA), 1999	Establishes a regulatory framework for Supply Chain Management, which includes procurement in national and provincial departments and state-owned enterprises.
Preferential Procurement Policy Framework Act, 2000	Section 217(3) of the Constitution requires that national legislation prescribe a framework within which the preferential procurement policy must be implemented This Act was drafted in response to this constitutional requirement. It establishes the way preferential procurement policies are to be implemented.
Broad-Based Black Economic Empowerment (B-BBEE) Act, 2003	Establishes a code of good practice to guide the development of qualification criteria for issuing licenses or concessions, selling state-owned enterprises, and forming partnerships within the private sector, with focus on those historically disadvantaged. It provides guidance for creating and implementing a preferential procurement policy.
Municipal Financial Management Act (MFMA), 2003	Establishes a regulatory framework for Supply Chain Management in municipalities and municipal entities
Policy Strategy to Guide Uniformity in Procurement Reform Processes in Government, 2003	Harmonises the interpretation of preferential procurement legislation across government. It modernises outdated procurement practices by implementing a supply chain management approach aligned with international best practices and establishes a regulatory framework (under the PFMA and MFMA) that ensures compliance while respecting cooperative governance principles.

[3] With technical and financial support from a World Bank IDF Grant, a Task Force was established in 1995 to create an efficient public procurement system for the national economy. The Task Force was led by the State Tender Board under the Ministry of Finance and the Department of Public Works, following the establishment of the new government after the 1994 elections.

National Treasury Regulations on Procurement, 2005	Backing the PFMA and MFMA, gives accounting officers control over a unified Supply Chain Management (SCM) system. They define SCM elements, require SCM units, detail bidding roles, address SCM abuse, and mandate performance reporting. They set minimum standards for supply chain and preferential procurement.
Local Procurement Accord[4], 2011	Recognised the pivotal role that local procurement can play in national development and economic growth, and in combating inequality, poverty, unemployment and rural underdevelopment. Aimed to mobilise all local stakeholders to promote local procurement and achieve a 75% localisation in the procurement of goods and service, and creation of 5 million new jobs by 2020. The accord sets out the first steps to achieve the target.
Preferential Procurement Regulations, 2011	Assists Accounting Officers/Accounting Authorities in implementing PPPF 2000/B-BBEE 2003, in conjunction with other relevant supply chain management guidelines. The guide covers various aspects such as preference point systems, evaluation of bids, local production and content, and B-BBEE status level verification certificates.
Office of the Chief Procurement Officer (OCPO)	Established in 2013 within the National Treasury. Responsible for the public procurement regulatory framework and policies; and ensures that procurement of goods and services adheres to the core procurement principles as spelt out in the constitution.
Strategic Procurement Framework, 2016	Provides guidance for strategic procurement within the public sector, combining private and public sector techniques to stabilise procurement, deliver quality services, drive value for money, and enhance socio-economic outcomes.
Preferential Procurement Regulations 2017[5] (An update)	Introduced significant changes including empowering institutions to utilise prequalification for preferential procurement, raising preference point system thresholds to R 50 million, mandating subcontracting for tenders above R 30 million to advance specific groups, and granting negotiation powers to institutions for fair pricing with preferred tenderers
Strategic Procurement Framework 2024 (An update)	The second version and an update of the 2016 SPF. The 2024 update includes social values in line with the Reconstruction and Development Programme (RDP) from 1994, sourcing business model mapping selection, and procurement methods.
Public Procurement Act, 2024	Provides guiding principles and approaches to public procurement of goods and services

2.2 Procurement activities at the different levels of government within South Africa

South Africa's health procurement landscape is shaped by a multifaceted set of processes striving to balance cost-effectiveness, adhere to government policy at both national and sub national level, and the constitutional mandate to provide healthcare to all citizens.

At the national level, the National Department of Health (NDoH) oversees the procurement of medical supplies through an open centralised mechanism, aiming to achieve economies of scale and standardisation across the public health sector. The NDoH provides technical expertise to provinces regarding writing tender specifications, verifying provincial estimates, preparing tender documents, receiving and reviewing estimates from the provinces for each tender contract, and monitoring supplier performance after award. Specifically, NDoH's Affordable Medicines Directorate coordinates tenders for medicines nationally, as provided for by the National Medicines Policy, and in collaboration with the National Treasury. In its coordinating role, contracts with pharmaceutical suppliers are currently entered into by the NDoH on behalf of the provinces.

NDoH works closely with the National Treasury for all contracts awarded. The Office of the Chief Procurement Officer (OCPO) created in 2013, sits at the National Treasury and is responsible for the public

[4] A non-legal binding instrument signed by the government, labor group and business community in 2011.

[5] The 2017 regulations were suspended by a Constitutional Court judgment on February 16, 2022. However, the court advised that the regulations would remain in effect until January 15, 2023. To address the shortcomings identified by the court, the National Treasury drafted the Preferential Procurement Regulations 2022. These 2022 regulations were intended as a placeholder, as a Public Procurement Bill, which was to include provisions addressing preferential procurement, was being finalized. These regulations are still in place (2025).

procurement regulatory framework and policies. This office works closely with all other government institutions to ensure that procurement of goods and services are done in accordance with the core procurement principles as provided for in the constitution and other legal procurement provisions. The National Treasury also manages the tender platforms – Central Supplier Database (CSD) and eTenders public portal. The portal carries tender notices, accompanied by official tender documents and relevant terms of reference (Bowmans, 2016). Registration on the CSD is also a prerequisite for any company aiming to engage in business transactions with the government at any level.

Provincial health departments manage procurement for services and supplies specific to their regions, allowing for localised decision-making and responsiveness to regional health needs. Following the NDoH award of contracts, as stated above, provincial-level medical stores oversee the quantification and procurement of pharmaceuticals for facilities within their respective provinces. They are also tasked with warehousing and distributing medicines.

In addition to the contracts awarded at the national level, provinces can still procure medically related items on provincial tenders, as provided for by the National Medicines Policy. Provinces procure the majority of their commodities through national contracts accounting for at least 90 percent of total spending. These contracts usually run for 2-3 years and specify indicative volumes, but don't require provinces to commit to minimum purchase quantities. The primary commodities procured through these contracts are for HIV, tuberculosis, and cancer treatments (Dubois, *et al.,* 2020). The structure of pharmaceutical services is however not uniform among the provinces. Provinces, like Mpumalanga, Limpopo and North West have in the past outsourced procurement, warehousing, and distribution services to private contractors (NDOH, 2010). While provincial medical stores are in charge of distributing medicines to health facilities, provinces are increasingly relying on direct delivery of medicines from contracted manufactures (suppliers) to health facilities, which shortens the supply chain [Babar 2017; Modisakeng, *et al*., 2020).

Procurement for **District health services** is centralised at the Provincial Department of Health, rather than being managed independently by individual districts. However, districts operate under a delegated procurement system with varying limits based on the level of the procuring entity. Procurement at the district level is capped at R500,000 for general district procurement and district offices and R200,000 for district hospitals (Karume, *et al.,* 2021).

2.3 Regulatory framework of public procurement

The procurement of medical supplies and health-related services is undertaken within the regulatory environment that provides for general procurement of goods and services by public institutions. There is no specialised regulatory framework for procurement within the health sector and institutions thus rely on different pieces of law that regulate public procurement. The regulatory framework is therefore a highly fragmented one, consisting of a range of constitutional and statutory provisions that were only loosely connected within the overall regulatory scheme (Quinot, 2014). However, the new Procurement Act (2024) aims to address this fragmentation once it is fully enacted into law.

Below is a review of the current main provisions of laws and policies relating to public health procurement, whilst also highlighting potential considerations when considering joining a regional pooled procurement mechanism.

a) The Constitution of the Republic of South Africa (1996)

The Constitution provides the foundation under which all procurement laws are anchored. It ensures adherence of overriding principles[6] - fairness, equity, transparency, competitiveness and cost effectiveness - applicable to public procurement that procuring entities in South Africa must follow. It

[6] There may be situations where one principle can only be met at the expense of another. As such, when determining compliance with section 217 of the Constitution, the five principles must be assessed holistically rather than individually (Bowman, 2016)

emphasises the conduct of the procurement process itself rather than their outcomes. The procurement process should, for example:

- Demonstrate fairness and not unnecessarily apply qualification requirements that exclude bidders, as well as provide sufficient time for bidders to respond to a tender.
- Maintain equal treatment of bidders by ensuring that procurement guidelines apply universally to all the bidders.
- Exhibit transparency, openness and accountability throughout the procurement lifecycle. The procurement process, including the publishing of information regarding tenders, must be made publicly, and decisions must be open to appropriate scrutiny.
- Ensure competitiveness by mandating procuring entities to acquire goods and services at the lowest price possible while ensuring value for money (Bowmans, 2016).
- Ensure contracts awarded achieve their intended outcomes in a cost-effective manner that delivers benefits for the population.

In addition to the guiding principles, Section 217 (2) of the Constitution sets the stage for using procurement to achieve policy objectives. It gives powers to the organs of the state or institutions to implement procurement policies in advancement of the policy goals aimed at protection or advancement of persons, or categories of persons, disadvantaged by unfair discrimination. These clauses have been instrumental in creating acts and policies such as Preferential Procurement Policy Framework Act (2000), which contains a framework for the application of preferences in the public sector bidding system and applicable to the public sector procurement system of all organs of the state in the national, provincial and local spheres of the government. Similarly, the Broad-Based Black Economic Empowerment Act (2003) provides a broad-based charter and issue codes of practice that could include qualification criteria for preferential procurement and other economic activities.

The Constitution also lists "health services" as a functional area of concurrent national and provincial legislative competence. This means that both national and provincial legislatures have the power to make laws regarding health services, which could include legislation regulating the procurement of health-related goods and services within their respective spheres. Additionally, Part B of Schedule 4 includes "municipal health services" as a local government matter to the extent set out in Section 155 (6) (a) and (7), indicating that municipalities may also be involved in health service provision and thus, potentially, health procurement. However, under the National Health Insurance Act (2023), a central Fund will be established that intends to act as a single purchaser of health care services. As such, this will lead to the centralisation of health service provision.

Considerations for joining a regional pooled procurement mechanism

Under the Constitution of the Republic of South Africa (1996), no explicit clauses were identified regarding pooled procurement in South Africa. However, procurement principles of *fairness, equity, transparency, competitiveness* and *cost effectiveness* will influence procurement policies and practices.

b) The Public Finance Management Act[7] (1999)

The PFMA (1999) is currently the primary legislative framework governing public procurement at both national and sub-national levels. It provides a devolved framework of financial management by decentralising financial and procurement responsibilities to the accounting officers at the provincial level.

The Act imposes specific legal requirements regarding public procurement. Accounting officers are mandated, according to Section 38(a) (iii), to create an appropriate procurement and provisioning system which is fair, equitable, transparent, competitive and cost-effective, as laid out in the Constitution. Furthermore, Section 76(2) empowers the National Treasury to issue regulations and instructions for

[7] Amended March 2017.

departmental procurement frameworks, ensuring adherence to the principles outlined in Section 38(a)(iii). As a general note, it also provides that the Preferential Procurement Policy Framework Act (2000) and its regulations shall apply to all public entities listed therein. Health-specific entities found within Schedule 3 of the Act include the National Health Laboratory Service, involved in providing public health laboratory services, and the South African Health Products Regulatory Authority (SAHPRA) which is responsible for regulating health products. Currently, there are no explicitly health-focused entities listed in Schedule 2 of the Act.

Considerations for joining a regional pooled procurement mechanism

The PFMA (1999) does not contain specific details about health procurement processes or pooled procurement. However, it establishes that health public entities are subject to national and provincial procurement legislation ensuring adherence to the general guiding principles as well as the other legislation such as the Preferential Procurement Policy Framework Act (detailed further below.

c) Municipal Financial Management Act (2003)

The legislation was enacted to facilitate sound and sustainable management of financial affairs for municipalities and other local government institutions. The procurement provision in the Act is aligned to the PFMA (1999), in that individual municipalities are required to implement a supply chain management policy that is fair, equitable, transparent, competitive, and cost-effective, but offers a more detailed and comprehensive framework for its procurement system (Watermayer, 2011).

The supply chain management policy, under Section 112, is aimed at governing the procurement of goods and services and the disposal of surplus products. A component of the supply chain management policy includes open and transparent pre-qualification processes for tenders and bids, with competitive bidding processes limiting participation to pre-qualified individuals.

Section 37(1)(a) mandates municipalities to promote cooperative governance in accordance with both the constitution and the Intergovernmental Fiscal Relations Act on matters of fiscal and financial relations. It also allows municipalities to enter into service delivery agreements with other municipalities or municipal entities.

Considerations for joining a regional pooled procurement mechanism

The MFMA (2003) allows municipalities to promote cooperative governance and enter pooled procurement agreements with other municipalities to achieve economies of scale and reduce associated costs. This can be interpreted as permitting participation in national or regional pooled procurement mechanisms, as long as this aligns with broader procurement principles.

d) The Procurement Act (2024)

Assented to law in July 2024 and awaiting enactment, this law is aimed at streamlining and consolidating the highly fragmented legislative landscape currently governing public procurement, including the replacing the PPPFA (2000). It governs all procurement carried out by a procuring institution, including procurement through donor or grant funding, and applies to anyone submitting a bid or awarded a contract.

Section 4 of the Act will establish the Public Procurement Office (PPO) within the National Treasury. The office will promote compliance by procuring institutions and support the implementation of measures to ensure transparency and standardisation in procurement, among other roles. The PPO will thus only provide oversight over the procurement system and will not be engaged in actual procurement. The Act further grants provincial treasuries significant additional oversight functions over public procurement. They can monitor and oversee the implementation of the procurement function by procuring

institutions within their province, promote effective management and transparency, and enforce procurement standards.

The Act provides a framework for preferential procurement (replacing the PPPFA (2000) as it requires procuring institutions to develop and implement a procurement policy that must include categories of preference in the allocation of contracts and the protection or advancement of persons disadvantaged by unfair discrimination. It further instructs the setting aside of bids for specific categories of persons to promote their participation in the economy.

The Act sets out various requirements for both suppliers and the goods they supply to the South African market. For suppliers, key requirements include being registered on the Public Procurement Office's database and making a prescribed declaration of interest. Suppliers must exercise due diligence to identify any automatically excluded individuals or related parties and must not exert undue influence on the procurement process. Compliance with the Act, its instructions, guidelines, and codes of conduct is essential.

Where applicable, suppliers must adhere to designations for local production and content. Furthermore, suppliers should contribute to transformation goals, advancing previously disadvantaged individuals and promoting economic transformation within black-owned and managed enterprises. Subcontracting is encouraged to further these aims. All quotations must be in South African currency, inclusive of all applicable taxes.

Regarding goods, the Act emphasises local production and content (Section 20), with the relevant Minister designating sectors and setting minimum thresholds. The Minister responsible for trade, industry and competition (referred to as "the responsible Minister") is the authority tasked with stipulating the minimum thresholds for local production and content. Goods supplied must meet required functionality and technical standards. Measures to advance sustainable development, job creation, labour absorption, beneficiation, and innovation are encouraged. The procurement system should utilise standardised and interoperable open data, promoting transparency and accessibility. When considering local (or national) production, a pooled procurement mechanism can support the aims of this objective by amplifying the consolidation of local demand envisioned under Section 20 of the Act, creating greater transparency of anticipated demand, thus providing a more stable and significant market for local manufacturers within South Africa. This will, however, require consideration of the stipulated minimum thresholds for local production and content that will guarantee that local manufacturers are capable of meeting the aggregated demand and quality standards, and where needed, the government may support with waivers necessary to strengthen the local capacity production. However, participating in regional pooled procurement mechanisms may not permit a local production and content clause, as previously discussed, and should restrictions be desirable, will more likely permit participation based on regional production.

When determining the specific share (percentage or value) of the minimum threshold, the responsible Minister must take into account several critical factors in addition to the public comments (section 20 (3)). These include assessing whether there are sufficient local manufacturers in the country capable of competing for the provision of the designated goods. This assessment considers the number of existing manufacturers, their security and ability of supply for the duration of the designation, and the contribution of other participants in the supply chain, such as distributors and product agents. Furthermore, the Minister must consider the effect of local production and content on employment and the economic impact on goods that would otherwise be imported. The Act also provides that the number of sufficient local manufacturers must be determined by the Minister, but it cannot be less than three local manufacturers.

Once a sector is designated and its minimum threshold stipulated, any procuring institution must advertise bids with a clear condition that only locally produced or manufactured goods meeting this threshold will be considered (section 20(5)). A bid that fails to satisfy this minimum local content threshold is deemed unacceptable and must be disqualified. However, the Act acknowledges the need for flexibility - *if a procuring institution cannot wholly source the required quantity of designated goods*

from local manufacturers or cannot meet the threshold for the specified period, it may request a waiver from the responsible Minister. The Minister must therefore respond to such a request within 30 days, providing reasons for their decision, otherwise, the waiver is automatically granted. The responsible Minister can also issue a general waiver by notice in the Gazette if circumstances warrant procuring below the stipulated thresholds.

Beyond setting the thresholds, the government, through the responsible Minister, provides ongoing support and oversight for local manufacturing. The Minister is mandated to monitor the impact of any designation and must publish a report on its impact on the departmental website three years after the designation. At least 12 months after this report is published, the responsible Minister may review the appropriateness of the designation, its threshold, and its period, and amend or withdraw them if the review's outcome requires it. This structured, dynamic approach ensures that the local production policy remains adaptable to market realities and continues to align with national development and industrial policies.

Pooled procurement is implied under Section 24 of the Act, in which authority is bestowed upon the minister to develop a framework that seeks to promote strategic procurement. It includes procurement in other countries for use in those countries; for infrastructure, capital assets and goods or services related to maintenance of infrastructure and capital assets; for the disposal and letting of assets; and to stimulate innovation. However, at present, this does not appear to permit the inclusion of health-related procurement and therefore may need an amendment to the legislation or further clarity in the upcoming procurement regulations. Once this piece of legislation has been fully enacted along with the upcoming procurement regulations, they will provide the primary procurement guidance that must be followed when conducting public procurement. At present the regulations have not been drafted and therefore it is not possible to define the specific requirements that will be laid out when considering joining a regional pooled procurement mechanism. Therefore, it would be beneficial for the Department of Health and National Treasury to engage during the drafting process to provide guidance on any specific requirements.

Considerations for joining a regional pooled procurement mechanism

There are a number of key considerations under this piece of legislation that must be factored when seeking to join a regional pooled procurement mechanism, including:

- Alignment of South Africa's existing legislation, especially regarding preferential procurement and local content with any specific requirements of the proposed regional pooled procurement mechanism.
- Clarity on the roles and responsibilities of different entities, such as the Health Products Procurement Unit and the National Health Insurance Fund to determine who will manage South Africa’s participation in such a regional mechanism.
- Harmonisation of the reporting and financial standards with the requirements of the regional pooled procurement mechanism.
- Balancing and understanding the benefits of regional pooled procurement, such as cost savings and increased access to health products, with potential challenges related to local supplier participation and adherence to national preferences.
- Engagement with the preparation of the upcoming procurement regulations that will allow for participation in a regional pooled procurement mechanism.

A detailed review of both African Union pooled procurement and SADC pooled procurement mechanisms is provided under section 4.

e) Preferential Procurement Policy Framework Act (PPPFA) (2000)

The Act gives effect to Section 217 (3) of the constitution by providing a framework for public institutions to implement a preferential procurement policy. These institutions are mandated to establish and implement preferential procurement policies using a preference point system. Under the guidance provided within the Act, the system involves allocating points for both price and specific goals under its evaluation criteria when determining the evaluation score. The Act sets parameters for these allocations, with a maximum of 10 or 20 points available for specific goals, depending on the anticipated value of the procurement. Specific goals must be measurable, quantifiable and monitored for compliance. The Act also empowers the Minister of Finance to make regulations deemed to be necessary to achieve the broader objectives of this Act.

Regulations have been put in place to implement the PPPFA. There have been several revisions of these regulations, most recently the 2022 Preferential Procurement regulations (PPR 2022), which has raised the procurement values when determining which preferential points system to utilise. For proposed procurement values 'equal to, or below R50 million' the 80/20 system is to be used and where the value exceeds R50 million the 90/10 system is the appropriate approach.

The PPR 2022 specifically provides for allocation of preference points based on specific goals chosen by an organ of state. Specific goals include contracting with persons or categories of persons, historically disadvantaged by unfair discrimination on the basis of race, gender and disability including the implementation of programmes of the Reconstruction and Development Programme[8] (RDP), promotion of Small, Micro and Medium-sized Enterprises (SMME) or inclusion of local content. The PPR 2022 does not set specific goals for local content and production. This is determined by individual institutions, not the Minister of Finance, as per a prior Constitutional Court ruling. It should also be noted that the Minister of Finance retains the power to grant exemptions under specific circumstances, such as considerations of national security or the nature of the tenderers. In this case, institutions are therefore advised to consult the Reconstruction and Development Programme document to identify specific goals related to local content/ industrialisation for which points may be allocated in the invitation of tenders.

Additionally, the Broad-Based Black Economic Empowerment Act (B-BBEEA) of 2003, provides a framework for measuring and incentivising broad-based black economic empowerment compliance by businesses, including through preferential procurement. It therefore provides the criteria and targets for achieving black economic empowerment. State organs thus use B-BBEE compliance as one of the "specific goals" in their preferential procurement policies under the PPPFA. This means that businesses with higher B-BBEE status levels may receive more preference points in government tenders. Whilst regional pooled procurement methods may include their own preference policies, they will likely need to be applied across all participating member states and therefore will be more regional in their focus.

Some aspects of the PPPFA and its regulations could be interpreted to relate to or allow for elements of pooled procurement, particularly through the promotion of specific goals and the empowerment of certain enterprises. Section 2 requires organs of state to determine their own preferential procurement policies within the Act's framework. This autonomy could be interpreted as allowing organs of state to collaborate voluntarily and design joint procurement strategies, including pooled tenders, provided they comply with the Act's core principles (e.g., the preference point systems). However, when considering a regional pooled procurement mechanism, achieving the goals as stated in the PPPFA will be dependent on the specific aims of the mechanism.

Considerations for joining a regional pooled procurement mechanism

The inclusion of local content as either a selection or evaluation criteria in the procurement process may not be possible, as the pooled procurement mechanisms span regional countries and such a policy would exclude suppliers from those countries from participating. In this case, an approach that restricts participation to suppliers from countries participating will be more likely. With the legislation currently mandating the use of the preferential procurement, there may need to be an amendment or further guidance that permits the exemption of this approach should it not align with the specific objectives of the regional pooled procurement mechanism.

f) Medicines and Related Substances Act (1965)

The Medicines and Related Substances Act came into effect in 1967. It is the main legal framework that provides for the registration of medicines and related substances, serving to regulate those intended for both human and animal use. It establishes the South African Health Products Regulatory Authority [SAPHRA] (formerly the Medicines Control Council), defining its role and outlining its functions.

This Act aims to improve access to affordable medicines in South Africa. It achieves this by addressing key areas such as regulating the registration of approved medicines, and in vitro diagnostic (IVDs) (Section 15), council or committee member disclosure of commercial interests, and medicines control (Section 22A), as well as procedures for appeals. Further, the Act stipulates requirements for label approval, prohibits the distribution of drug samples and bonuses, and governs the licensing of entities involved in medicines compounding, dispensing, manufacturing, and distributions. Additionally, it covers generic substitution under Section 22F, allowing for dispensers to offer a generic alternative to expensive, branded medicines, so the patient can make an informed choice. All of these factors will have a critical influence on the participation in a regional pooled procurement mechanism, providing specific requirements that must be adhered to when supplying to the South African market. It will therefore be key for the South African government to discuss these with the respective institutions managing the regional pooled procurement mechanisms to look at opportunities to align to ensure compliance.

The Act also establishes a pricing committee under Section 22G, integral to health procurement. The pricing committee empowers the minister to formulate a transparent pricing system by wholesalers or distributors (Competition Commission South Africa (2023). The transparent pricing system includes a single price which sets the prescribed maximum price that manufacturers can sell prescription medicines to any person other than the State (Section 22G 3 (a)). Additionally, the pricing system incorporates the logistic fee, which is determined through a negotiation process, paid by the manufacturer to the logistic service provider for the distribution of the medicine from the manufacturer or importers premises to end dispensers. The logistics fee is also regulated, and a maximum fee is set (logistics fee cap). The Minister of Health determines the extent to which the medicine prices may be adjusted on an annual basis, in addition to setting a cap on the logistics fee. Any prices established under regional pooled procurement approaches will need to consider the maximum prices set. However, should prices exceed the maximum values set, it is unlikely to present value for money, and the products will not be procured through the mechanism.

The Act has provisions that directly and indirectly regulates the procurement of medicines and related products, specifically addressing availability and affordability. International tendering is allowed under Section 1(4) in the prescribed manner and conditions and aims at securing more affordable medical supplies. Similarly, to protect public health, the Minister of Health is empowered under Section 15C to prescribe conditions for the supply of affordable health products, and as such may allow for parallel importation as a procurement strategy for affordability purposes. The Act allows the minister to assess and waive the rights of the medicine patent, that ensures that the patent does not prevent importation of the health products as long as the health products originates from an approved manufacturing site of the original manufacturer and is imported by someone other than the registration certificate holder. Section 35(1)(xvii) and (xviii) relate to the importation, exportation, and transhipment of medicines and related substances from international sources to South Africa. This will also need to align to the specific requirements laid out in the regional pooled procurement mechanism to ensure the appropriate measures are in place when importing these goods into South Africa.

Considerations for joining a regional pooled procurement mechanism

This piece of legislation provides conditions for the supply of health-related products and therefore must be adhered to when assessing the appropriateness of joining an international pooled procurement mechanism. Although we anticipate that international suppliers could adhere to the specific labelling and other packaging requirements stipulated as well as importation requirements, it would be advantageous to have these factored in as part of the tender process when establishing

g) National Health Insurance (NHI) Act (2023)

Assented to law in May 2024 although yet to come into force, the National Health Insurance Act establishes a National Health Insurance Fund to provide universal access to quality healthcare services, as per Section 27 (1) (a) of the constitution. The Act focuses on financial protection from healthcare costs by pooling public revenue to strategically purchase healthcare services and creates a single framework for public funding and purchasing of healthcare services, medicines, and related products, eliminating fragmentation in healthcare funding.

Centralisation of Procurement Activities

The Act establishes several bodies to oversee the procurement and funding of healthcare services:

- A Benefits Advisory Committee (BAC) to determine the scope of healthcare services offered.
- A Health Care Benefits Pricing Committee to determine what the NHI Fund should fund and the available services included.
- A District Health Management Office to co-ordinate the roll-out of primary healthcare (PHC) treatment at the district level.
- A Contracting Unit for Primary Healthcare (PHC) to contract with service providers at the district level.

The Act also envisions a Health Products Procurement Unit within the National Health Insurance Fund to centralise and coordinate the public procurement of health-related products. This unit will ensure cost-effectiveness and equitable distribution through strategic purchasing of healthcare services, medicines, and related goods from accredited providers, utilising standardised specifications. This centralisation is key to pooled procurement, as it allows for strategic purchasing of healthcare services, medicines, and related goods from accredited providers, utilising standardised specifications. This approach will ensure consistent quality and cost-effectiveness across the entire healthcare system.

Health care service providers and health establishments must be certified by the Office of Health Standards and Compliance and registered by a recognised statutory health professional council. They must also procure health products from the Formulary. Any pooled procurement mechanism must consider how health care providers will access products, including order quantification, placement, frequency, and payment facilitation.

Currently, the National Department of Health's Directorate of Affordable Medicines Directorate (AMD) and the Pharmaceutical Economic Evaluation Directorate is instrumental in handling procurement of health products. The department defines health products to include medicines, diagnostics, and devices as well as consumables. The AMD is in charge of systems that guarantee access to essential medical supplies, through regulation and implementation of standard treatment guidelines, contract management of awarded health products contracts, as well as licensing of persons or institutions for the delivery of medical supplies. The directorate also has a repository of Annual Single Exit Price Adjustment (SEPA) gazette notices, as well as any information or correspondence on International Benchmarking for medicines sold in South Africa, list of approved donations for medicines reported to the National Department of Health, approved exemptions granted in terms of Section 36(2) of the Medicines Act, and Pricing Committee documents. The AMD is therefore likely to be a key partner when considering the

requirements of joining a regional pooled procurement mechanism, particularly around defining qualification and specification requirements to ensure it meets the needs of the South African market.

The procurement processes are subject to public procurement laws and policies that give effect to Section 217 of the Constitution, including the Preferential Procurement Policy Framework Act, 2000, and the Broad-Based Black Economic Empowerment Act, 2003. This implies that suppliers must comply with all relevant regulations related to public procurement, including those related to preferential procurement and broad-based black economic empowerment.

Considerations for joining a regional pooled procurement mechanism

The NHIA Act suggests a commitment to efficient, large-scale (pooled) procurement practices through a centralized function and anticipates this will include activities including the alignment of standards and quantification of requirements. These activities will be key to successfully participate in a regional pooled procurement mechanism and therefore may offer a platform in which to build, but it also requires adequate cross-country alignment and political will for implementation. The centralization of procurement activities through the NHI fund could also act as the primary contact point and manage South Africa's requirements under a regional mechanism.

h) Disaster Management Act (2002)

The Act is centred around establishing an integrated and co-ordinated disaster management policy within South Africa. The main goals of the Act include reducing disaster risks, mitigating the intensity of disasters, ensuring readiness for emergencies, facilitating quick and effective responses, and promoting recovery after disasters. To achieve these objectives, the Act facilitates the establishment of disaster management centres at the national, provincial, and municipal levels. It calls for the creation of a National Disaster Management Centre, under Section 8, and mandates that each national organ of state, as outlined in the national disaster management framework, must formulate a disaster management plan. It designates specific responsibilities to different levels of government to ensure effective coordination and management of disasters and allows for the declaration of a national state of disaster.

The Act addresses procurement, particularly focusing on emergency procedures that may be enacted when a national state of disaster has been declared (Section 27 (2) (l)). In such instances, the responsible Minister is authorised to establish regulations or issue directives pertaining to emergency procurement methods. Each province and municipality is obligated to develop a disaster management plan tailored to the specific conditions within its jurisdiction, but must include contingency measures and emergency protocols that facilitate the procurement of essential resources and services (Sections 39 (2) (k) and 53 (2) (k)). The authority to allocate resources is strictly limited to what is deemed necessary for aiding and protecting the public, providing essential relief, and safeguarding property. The provisions of this Act permit the use of emergency procurement under specific circumstances.

Considerations for joining a regional pooled procurement mechanism

The specific requirements under which a country is exempted from using a regional pooled procurement mechanism must be considered. It would be advisable to include a clause that allows for the purchase of goods and services outside of the agreement under certain conditions, such as during an emergency. This allows procurement to be undertaken in accordance with the emergency procedures of this Act, as opposed to being restricted to purchasing through the mechanism

3 | A summary of South African and regional health sector manufacturing

KEY MESSAGES

- **South Africa possesses a significant health manufacturing sector but still remains heavily dependent on imports.** The local pharmaceutical market was valued at USD 4.6 billion in 2021, and the country serves as the primary hub for pharmaceutical production in Southern Africa with 122 local manufacturing plants. However, higher domestic production costs, combined with regulatory requirements for local participation in parts of the supply chain, have confined local manufacturing primarily to downstream activities such as packaging, sustaining a high dependence on imports that account for over 76% of medical devices.

- **The broader African region is a large, rapidly growing pharmaceutical market constrained by an underdeveloped manufacturing capacity.** Southern Africa, as a region, is expected to be the second-fastest growing sub-region on the continent by 2030, with South Africa currently accounting for over half of its medicine sales. Despite this market size, 80% of the continent's production is based in just eight countries and focuses mostly on fill-and-finish operations with minimal research and development or Active Pharmaceutical Ingredient (API) production, a deficit that the African Development Bank estimates will require USD 111 billion in investment by 2030 to resolve.

- **Multiple continental initiatives are actively working to incentivise local manufacturing and accelerate regulatory harmonisation across Africa.** Programmes such as the African Vaccine Manufacturing Accelerator (AVMA) offer downstream financial incentives to offset production costs, while the mRNA vaccine technology transfer hub in South Africa is building local production capacity for low- and middle-income countries. Additionally, the African Medicine Regulatory Harmonisation (AMRH) platform and the emerging African Medicines Agency (AMA) aim to implement unified technical standards, joint dossier assessments, and coordinated regulations to facilitate seamless cross-border market access.

- **Participating in a regional pooled procurement mechanism offers South African manufacturers expanded market access but also poses competitive and regulatory challenges.** While regional mechanisms could increase production volumes by opening access to an aggregated continental market, South African manufacturers might struggle to compete if contracts are awarded solely based on the lowest unit price, due to their higher baseline production costs. Furthermore, strict domestic regulations requiring suppliers to have an authorised representative resident in South Africa could act as a barrier for regional suppliers, highlighting the need for harmonised standards to facilitate true cross-border procurement.

As discussed in Section 2 above, South Africa has implemented preferential procurement policies including placing a focus on local production. This section looks at the current South African health sector, as well as the wider African region, including initiatives to grow the health sector manufacturing base. This will provide additional context when considering the potential impacts and opportunities for participating in a regional pooled procurement mechanism.

3.1 Health sector manufacturing in South Africa

The South African pharmaceutical industry has a market size valued at USD 4.6 billion (2021), with main productive segments being generics, biologics, biosimilars and over-the- counter (OTC) drugs (Monaco, L. and Habiyaremye, A., 2024). Similarly, the medical device market share was estimated at USD 1.43 billion (2021), making up only 0.3% of the global market for medical supplies. The manufacturing output of medical devices is estimated to be about USD 200 million to USD 300 million per year (2021), of which more than half are exported (SAMRC, 2022).

Our review highlights that there are a range of manufacturers within South Africa, however, there remains a reliance on imported products. In particular, South Africa has relatively limited production capacity for medical devices. The market is therefore largely dependent on imports (FitchSolutions, 2021), with more than 76% of devices being imported (SAMRC 2022).Reasons for this include the higher cost to manufacture locally, for instance, tendering practices allow for local preference to encourage domestic

firms, but in practice, these are often not able to compete on price. Additionally, in order to sell products in South Africa, international manufacturers are required to contract any part of the supply chain (formulation, packaging, warehousing, and distribution) to a local player (Dubois, et al, 2020). As such, this may lead to much of the local supply focused on downstream operations like packaging and fill-and-finish.

Although there are only 122 local pharmaceutical manufacturing plants in South Africa, the Department of Health and South African Health Products Regulatory Authority (SAHPRA) have registered 276 companies to manufacture, import or export, as well as to distribute pharmaceuticals (Institute for Economic Justice, 2022). Additionally, the medical devices landscape survey indicated that South Africa has at least 136 medical device manufacturing companies with substantial diversity in terms of size, turnover, products produced and levels of R&D expenditure. The markets consist of large multinationals, established local multinationals, emerging companies, and many small vendors. Among the established players is Aspen, the largest pharmaceutical manufacturer in Africa and the market leader in the prescription medicines segment.

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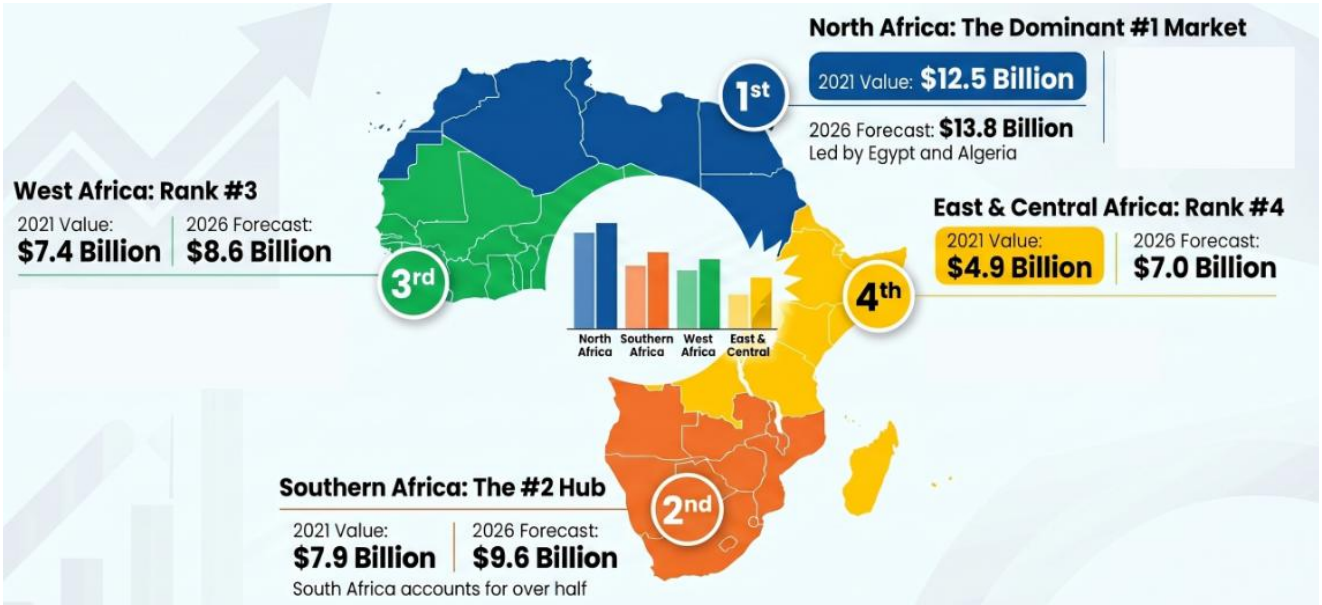
3.2 Regional manufacturing capacity

As a region, Southern Africa is the second largest market in Africa in terms of pharmaceutical spending after North Africa, and is projected to be the second-fastest growing sub-region by 2030, slightly below East & Central Africa, based on compound annual growth rate. Within the Southern Africa region, South Africa remains the largest pharmaceuticals market, accounting for over half of medicines sales in the region in 2021, at USD 4.3 billion. While annual pharmaceutical spending per capita is expected to reach USD 108 by 2030, South Africa will still lag the global average annual pharmaceutical spending per capita of USD 247 (Afrexibank, 2022).

Figure 2: Africa's pharmaceutical spending (USD) : 2021 -2026 Regional Market Outlook



Despite the size of the market, African manufacturing capacity is underdeveloped with 80% of the production based in eight countries. The focus is largely on downstream operations like packaging and fill-and-finish, with very little research and development (R&D) and minimal production of Active Pharmaceutical Ingredients (APIs) (G7, 2024). The African Development Bank (AfDB) estimates that, by 2030, an overall envelope of USD 111 billion would be needed in Africa in terms of investment through private and public sector interventions, of which USD 11 billion dedicated to the development of the pharmaceutical manufacturing industry, and USD 100 billion to develop supporting infrastructure (AfDB,

2022). A number of manufacturing initiatives are however being undertaken to incentivise and accelerate local manufacturing capacity. These initiatives include:

- **The African Vaccine Manufacturing Accelerator (AVMA)** – Supported by the Gavi, the Vaccine Alliance, AVMA is an instrument aimed at catalyzing the sustainable growth of vaccine manufacturing in Africa. It is designed to make up to USD 1.2 billion available over ten years (commencing with AVMA's launch in June 2024) to accelerate the expansion of commercially viable vaccine manufacturing in Africa. AVMA offers a 'pull financing mechanism' by providing downstream incentives to manufacturers to help offset initial costs of development and production. AVMA has a tiered incentive structure, with a payment of USD 25 million for any Gavi portfolio vaccine whose drug substance is manufactured in Africa on an AVMA Priority technology platform (mRNA and viral vector); USD 20 million for any AVMA Priority vaccines[9] whose drug substance is manufactured in Africa, and lastly, USD 10 million for AVMA Priority vaccines for which only 'fill and finish' takes place in Africa. There are also accelerator payments based on the dosage. Manufacturers may apply to Gavi for an AVMA eligibility assessment during the WHO prequalification process but only after the vaccine manufacturing site visit by WHO Inspection Services is completed (GAVI, 2025).
- **African Medicine Regulatory Harmonisation (AMRH) Partnership Platform** – AMRH is a programme of the African Union (AU) implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) to facilitate and coordinate the harmonisation of medicines regulation and improve access to quality, safe, efficacious and affordable medicines in five regions[10] across Africa. It thus creates a platform to build African regulatory capacity by region. It started in 2009 as a response to addressing challenges faced by National Medicine Regulatory Authorities (NMRAs) in Africa. The pathway envisioned by the AMRH begins with the implementation of harmonised technical standards and guidelines, coupled with joint regional dossier assessments and Good Manufacturing Practice (GMP) inspections to ensure consistency and quality.

  Building upon the AMRH, **the African Medicines Agency (AMA)** Treaty, adopted in 2019, was mandated to enhance the approval process for safe and high-quality medical products by facilitating collaboration and reliance mechanisms. It provides regulatory and scientific guidance for priority diseases, emerging diseases, and traditional medicines. The AMA will play a key role in enabling pooled procurement by spearheading the creation of standardised regulations for medical products across the continent. The South African Cabinet approved the signing of the AMA treaty in September 2022 and submitted it to Parliament for ratification[11]. As of March 2024, although there has been progress, only 27 out of the 55 African Union member states had ratified the treaty
- **mRNA vaccine technology transfer hub** - Launched in July 2021, the objective of the technology transfer hub is to build the capacity of low- and middle-income countries to produce mRNA vaccines through a centre of excellence and training, known as the "mRNA vaccine technology hub". The hub is located at Afrigen, in Cape Town, South Africa, and will work with a network of technology recipients (spokes) in low- and middle-income countries. The initiative is supported by WHO, the Medicines Patent Pool and the Act-Accelerator/COVAX. The South African hub comprises Afrigen Biologics, the South African Medical Research Council (SAMRC) and Biovac, a South African vaccine producer. Within this consortium, Afrigen is the entity mandated to establish mRNA vaccine production technology, SAMRC is providing the research and Biovac is the first manufacturing spoke.

[9] Oral cholera, Malaria, Measles-rubella, Hexavalent (wP), Yellow fever, Ebola, Rotavirus and Pneumococcal

[10] Southern African Development Community (SADC), East African Community (EAC), Intergovernmental Authority on Development (IGAD), Economic Community of Central African States (ECCAS), and Economic Community of West African States (ECOWAS)

[11] As of March, 2025, South Africa has not yet ratified the African Medicines Agency (AMA) Treaty.

3.3 Considerations for joining a pooled procurement mechanism

Whilst the current manufacturing capacity in South Africa is relatively small, it is the primary hub for pharmaceutical production in Southern Africa and has one of the highest numbers of local manufacturing plants on the continent. As such, this provides opportunities to grow the market through greater access to regional markets that participating in a regional pooled procurement mechanism will offer. However, as stated above, local production is limited due to higher production costs, and the market remains largely reliant on imports. It will therefore be key to understand the specific objectives of the regional pooled procurement mechanisms tender approach to understand any impact that joining such a mechanism will have on the local manufacturers. Where the primary objective is lowest cost, this would suggest that South African suppliers, with a higher cost base, will be uncompetitive. However, where the regional pooled procurement mechanisms implement a preference or set-aside for regional manufacturing, South African manufacturers will be in a more favourable position. It should be noted that this report does not provide an analysis of the competitiveness of the South African health sector manufacturers in the regional market.

Additionally, as per the South African Health Products Regulatory Authority (SAPHRA), only authorised representatives resident in South Africa may apply for registration of products with SAHPRA. As such, this may create a barrier to participation for suppliers on a regional pooled procurement mechanism that do not have a presence within South Africa or place additional cost on the supplier. This may therefore require harmonisation or mutual recognition of standards to facilitate market access. A more detailed analysis is provided under sections 5 and 6 below.

4 | Overview of Pooled Procurement Mechanisms

KEY MESSAGES

- **The Southern African Development Community (SADC) Procurement Mechanism provides a sub-regional approach to pooled procurement aimed at improving the availability and affordability of essential medicines through economies of scale**. The region is implementing the SADC Pooled Procurement Services (SPPS), with Tanzania selected to host the coordinating entity in 2018. Participation requires member states to commit to aligning their national medicines policies, supply management standards, and legal instruments with SADC protocols to enable a unified approach to prequalifying suppliers and establishing regional framework contracts.

- **The rollout of the SADC Pooled Procurement Services (SPPS) utilises a flexible, phased implementation strategy but currently faces several operational and political challenges.** The SADC strategy is designed to progress gradually from coordinated information sharing and the exchange of regional good practices to the establishment of the SPPS coordination entity and joint regional tendering. However, the mechanism remains in its early stages of expanding participation and has experienced setbacks due to weak political will, unclear accountability, inaccessible pharmaceutical information, and a lack of standardisation regarding procurement and pricing data across the region.

- **The African Union Pooled Procurement Mechanism (APPM) is an emerging continental initiative designed to simultaneously improve access to affordable health products and stimulate local African manufacturing**. Formally endorsed in February 2024 and currently in its pilot phase, the APPM aims to reduce Africa's heavy reliance on imported medical supplies, as imports currently account for 99% of the continent's vaccines. Through aggregation of procurement needs, harmonisation of regulatory laws, and the use of collective bargaining power, the mechanism seeks to lower costs, strengthen manufacturer confidence, and ultimately achieve the African Union's goal of producing 60% of the continent's vaccine needs locally by 2040

- **The implementation of the APPM relies on a structured, four-part roadmap that progressively shifts from foundational coordination to fully centralised regional procurement.** The roadmap begins with establishing institutional arrangements and stakeholder commitments, followed by creating a digital platform for sharing market intelligence, demand forecasting, and supplier performance data. It then advances into negotiating group contracts to secure volume-based pricing and culminates in institutionalising a governing agency to manage bulk procurement, storage, and a hub-and-spoke distribution network across participating countries.

Building upon the examination of South Africa's health procurement landscape, regulatory framework, and potential barriers to regional cooperation, this report now considers two specific pooled procurement mechanisms: the African Pooled Procurement Mechanism (APPM) and the Southern African Development Community (SADC) Procurement Services (SPSS), the mechanisms through which South Africa has a direct institutional pathway through its existing memberships. The APPM is the continent-wide mechanism endorsed by the African Union and led by Africa CDC, established to consolidate demand across member states and improve the affordability and security of supply of essential medicines, while the SPSS operates at the regional level within the Southern African Development Community, the regional bloc to which South Africa belongs. Confining the assessment to these two reflects the level at which meaningful pooling is realistically available to South Africa: the continental tier (APPM) and the regional tier (SPSS).

This section will provide an overview of each mechanism, highlighting their key features before identifying considerations specific to joining these two mechanisms. Understanding the structures, objectives, and operational approaches of the APPM and SPSS will help assess their implications for South Africa, identify areas for harmonisation, and inform next steps in evaluating the feasibility and benefits of participation.

4.1 African Pooled Procurement Mechanism (APPM)

Africa is heavily reliant on external vaccines, with imports accounting for 99% of its vaccines and consuming 25% of global vaccine supply (Wellcome, 2023). Efforts by the African Union to consolidate and improve local capacities of African states saw a launch of Pharmaceutical Initiative (Pharma Initiative) in November 2019, anchored under African Continental Free Trade Area (AfCFTA). The Pharm-Initiative adopted a three-pronged approach, consisting of Localised Pharmaceutical Production (LLP), Pharmaceutical Pooled Procurement (PPP), and a harmonised regulatory and quality standard framework. Under Phases I and II of the Pharma Initiative, which ran from November 2019 to May 2023, UN's Economic Commission for Africa (UNECA) and partners produced a framework for implementing centralised pooled procurement in 10 pilot African countries[12], with specific focus on key reproductive, maternal, newborn and child health pharmaceutical products to demonstrate proof of concept (UNECA, 2023).

In light of the UNECA's framework, the African Union Heads of States and Governments in their 37th Ordinary Session of February 2024 formally endorsed establishment of the African Pooled Procurement Mechanism (APPM) as the continental pooled procurement mechanism for health products. The APPM is currently under pilot phase and is yet to be rolled out. In May of 2024, African Ministers of Health, Finance and Trade, and development partners adopted an approach towards transitioning the AfCFTA-anchored Pharma Initiative (discussed above) into the start-up stage of the African Pooled Procurement Mechanism (APPM).

The APPM aims to play a dual role of improving access to quality and affordable health product technologies as well as promoting the localisation of manufacturing. This Mechanism intends to achieve its aims through aggregating demand by uniting procurement needs from different countries which will boost manufacturers' confidence to invest in local production (Africa CDC, 2024). APPM will also seek to eliminate inter-country barriers by harmonising regulatory procurement laws across the member countries which will enable manufacturers to produce and distribute medical supplies with ease across the continent. APPM will seek to leverage locally manufactured health product technologies that meet global standards, in combination with strong collective bargaining power to help African countries achieve supply security and reduced costs. It also aims to improve access to quality, affordable health products for member states through equitable, ethical, and sustainable procurement strategies. In the post COVID-19 era, APPM aims to prioritise African suppliers for emergency response needs while promoting global market sustainability through collaboration in purchasing practices. This aligns with the Joint Emergency Preparedness and Response Action Plan (JEAP) jointly launched by Africa CDC and WHO in 2023, which among its priority areas of action is to stockpile emergency supplies at strategic locations, with a focus on utilising local suppliers to meet emergency needs. According to the Africa Health Research Organization (AHRO), 70% of response activities during emergencies relate to supply chain measures.

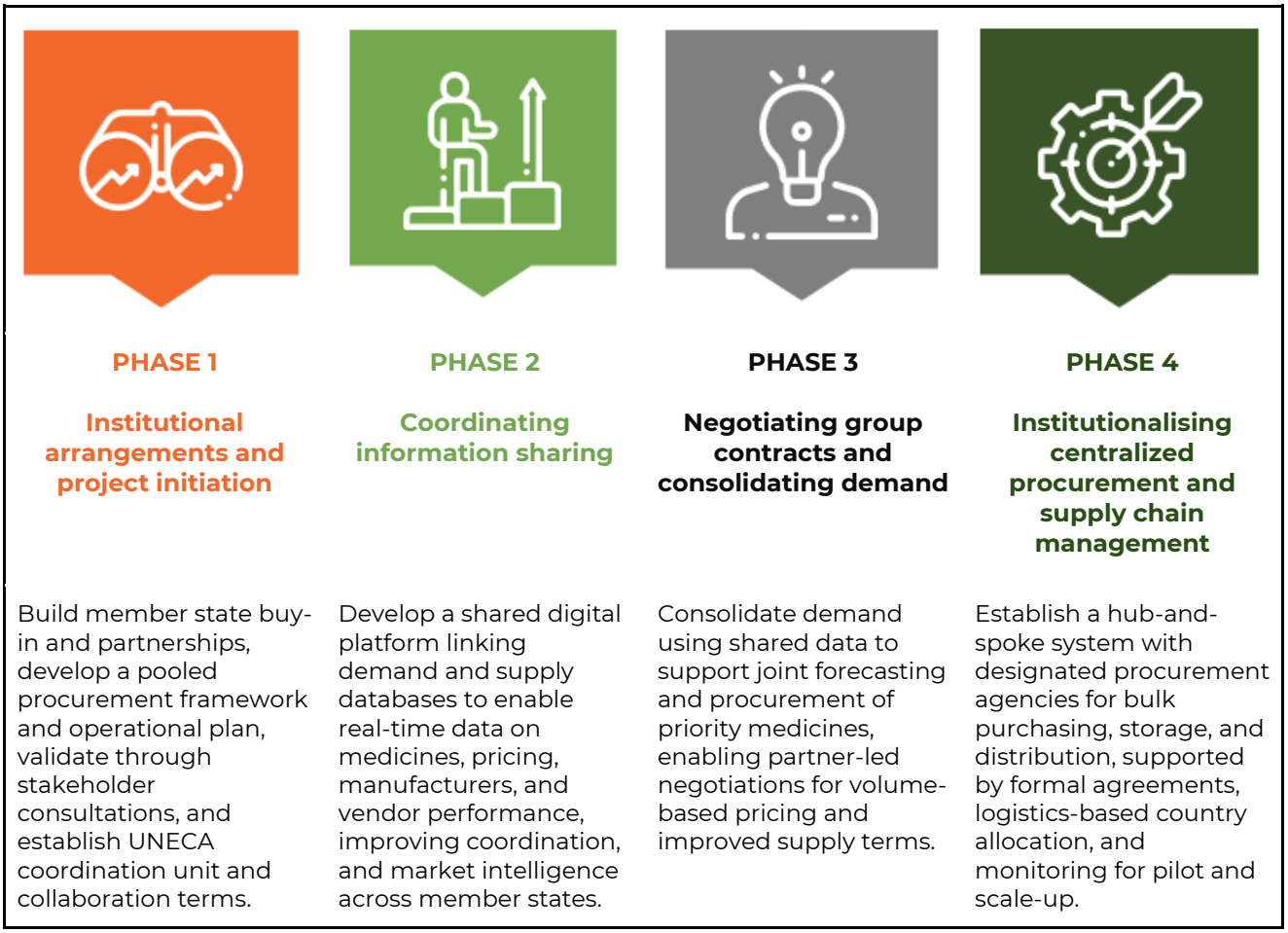
The APPM is being rolled out at the backdrop of African Union's ambition under the 'New Public Health Order' to produce 60% of the continent's vaccine needs in Africa by 2040, up from less than 1% in 2021 today (Africa CDC, 2024; Afreximbank 2024). The APPM aims to leverage on the learnings from the success of the African Medical Supplies Platform (AMSP), which was established in 2020 during the COVID-19 pandemic to facilitate volume aggregation and direct access to quality medical products for African governments. The AMSP operated as an e-commerce platform and connected medical suppliers directly with governments, donors and other stakeholders. This approach was done to cut costs involved and eliminate the reliance on intermediaries (ISS, 2021). The products were mainly essential medical supplies that were key in managing the spread of COVID-19; including personal protective equipment (PPE), diagnostic kits, ventilators, and vaccines. As such, the platform significantly improved access to essential COVID-19 medical supplies, enabling African countries to better respond to COVID. The platform, in collaboration with UNICEF, was also instrumental in delivering in excess of 25 million of procured vaccines to African countries in 2021. (AfrexiBank, 2021). However, limited African

[12] Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Rwanda, Sudan, Kenya, and Ethiopia.

manufacturing capacity of COVID-19 vaccines meant that majority of supplies were sourced externally, which were additionally constrained by global shortages and export bans (e.g. India's vaccine export ban) as well as from countries requiring upfront liquidity, which disrupted supplies.

The APPM implementation framework details a 4-part roadmap for its rollout as shown in figure 3 below:

Figure 3: APPM implementation roadmap



Overall, the African Pooled Procurement Mechanism (APPM) aims to increase access to affordable, quality health products and promote local pharmaceutical manufacturing. Whilst it is still in the early stages of its realisation, the African Union has developed a roadmap for implementation. The initiative aims to strengthen local production capacity across the continent and reduce purchasing costs by consolidating demand from member states to achieve economies of scale.

4.2 SADC Pooled Procurement Services (SPSS)

Southern African Development Community (SADC[13]) brings together 16[14] member states in the Southern Africa region. Pooled procurement was prioritised in the SADC Pharmaceutical Business Plan 2007-2013, and activities began in 2009 (SADC, 2021). Consequently, the region has been implementing SADC Pooled Procurement Services (SPPS) with phase one (2007-2016) involving the development of the strategy for pooled procurement of essential medicines and health commodities 2013-2017, development of a business case for pooled procurement; development of procurement savings report; and data base of suppliers and pricing in the region. This phase gave the basis for the full roll out of SADC Pooled Procurement Services.

[13] Founded in 1980 as the Southern African Development Coordination Conference (SADCC) but transformed into SADC to focus on economic development integration in 1992. SADC headquarters are in Gaborone, Botswana.

[14] Angola, Botswana, Comoros, Democratic Republic of Congo (DRC), Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Tanzania, Zambia, and Zimbabwe.

In 2018, the United Republic of Tanzania was selected to host SPPS and subsequently signed an MoU with the SADC Secretariat (SADC, 2019). Building on this, the Secretariat conducted a feasibility study on the SPPS. To facilitate effective implementation of SPPS, the study recommended a phased approach that allows for flexibility and national adaptation. This approach would enable countries to join the SPPS at a suitable time, aligning the initiative with their country procurement policies and regulations. It also emphasized the need to harmonize public procurement rules, laws, and procedures across member states, aligning them with international best practices. Based on these recommendations, the United Republic of Tanzania, with the Secretariat support, is now engaging additional member States to utilize SPPS services (SADC, 2022).

The **SADC Pharmaceutical Business Plan 2007-2013** outlined pooled procurement as a key tool to improve access to affordable essential medicines in the region. It aimed to: evaluate the options for pooled procurement for priority medicines and harmonise procurement regulations, identify the priority essential medicines which can bring about the largest savings from pooled procurement or price negotiations, and identify and facilitate access to funding sources and finance mechanisms for joint procurement. The cost for establishing the regional mechanism for pooled procurement was estimated at US$2 million, mainly to support processes and drafting of regional policy on agreement for pooled procurement.

Requirements to join the SADC pooled procurement include a commitment from member states, the inclusion of the pooled procurement mechanism within their National Medicines Policies (NMP) strategy, agreement on SADC pharmaceutical Procurement and Supply Management (PSM) standards, and having legal instruments aligned with the SADC Protocol on Health. Additionally, the SADC Secretariat is mandated to facilitate regional pharmaceutical pooled procurement, with the idea of establishing a SADC Pharmaceutical Pooled Procurement Institute to technically coordinate information and work sharing, monitor adherence to SADC policy guidelines, negotiate affordable prices, and ensure efficient procurement.

The **SADC Strategy for Pooled Procurement of Essential Medicines, 2013-2017** recommended a phased approach to pooled procurement:

a) Coordinated information sharing on medicines quality, prices, suppliers, availability and registration. This will be done through the establishment of electronic databases and platforms.

b) Development and implementation of agreed regional “good practices” in their procurement supply chain systems. The strategy defines "good practices" as agreed description of the pharmaceutical organisation, procedures and standards that enable the required quality of service to be delivered, including criteria for organisational structures, personnel, facilities, equipment, materials, all kinds of operations, and quality control

c) Coordinated work sharing through exchange of existing “good practices” among Member States, including standard operating procedures (SOPs), standard bidding documents, tender adjudication reports, storage conditions, and distribution schedules among Member State procurement agencies

d) Establishment of the coordination entity - The SADC Pharmaceutical Procurement Services (SPPS)

e) Regional tendering for prequalification of regional suppliers and products and;

f) Regional framework contracts with suppliers under which Member States purchase directly from suppliers (group contracting).

This mechanism is still in the early stages of development but is focused on expanding participation amongst its members. The mechanism’s objectives are primarily based on improving availability and affordability of essential medicines and health commodities across the SADC region through the consolidation of requirements across member countries to leverage economies of scale.

According to UNECA (2023), the SADC pooled procurement mechanism has experienced challenges related to weak political will on joint procurement, unclear road map, roles and accountability regarding implementation, information on pharmaceutical procurement being not easily accessible in the SADC region and lack of standardisation regarding procurement and price information. As such, all of these challenges will need to be addressed as part of its effort to roll the pooled procurement mechanism more widely.

4.3 Comparative analysis of APPM and SPSS mechanisms

Clear understanding of the relationship between these two mechanisms is required before South Africa can make informed commitments. The table below summarises Sections 4.1 and 4.2 and compares the mechanisms across key dimensions relevant to South Africa's decision-making.

Table 3: Comparative review of APPM and SPSS mechanisms

Dimension	APPM (Africa CDC Level)	SPSS (SADC Level)
Governance body	Africa CDC / UNECA (coordinating agency)	SADC Secretariat / Tanzania as SPPS host
Geographic scope	Continental (55 AU member states)	Regional (16 SADC member states)
South Africa's current status	Not in 10-country pilot; prospective participant	SADC member; not yet active SPPS participant
Product scope	Initial: maternal and child health; broader expansion envisaged	Essential medicines and health commodities
Manufacturing preference	Explicit AU mandate to prioritise African suppliers	Regional PSM standards; less explicit on preferences
Implementation stage	Pilot phase with 10 countries; not yet operational at scale	Early-to-mid stage; Tanzania-anchored MOU in place
Coordination between mechanisms	Both in development; product scope overlap; governance relationship unresolved	SADC mechanism may nest within APPM or operate in parallel
Financing model	Self-financing via fee-for-service or member contributions envisaged	Member fees from savings; initial multilateral partner support

5 | Barriers and opportunities to participation in a regional pooled procurement mechanism

KEY MESSAGES

- **South Africa must align its domestic legal framework and preferential procurement policies with the harmonised regulatory requirements of regional mechanisms**. Participating in regional platforms requires signing corporate agreements that demand harmonised procurement laws. As such, South Africa will need to address potential conflicts between its domestic preference policies, such as local content requirements designed to protect national manufacturers, and the rules of regional joint contracting.
- **Successful integration requires active data sharing and ensuring that South Africa's**

existing IT systems are compatible with regional intelligence platforms. South Africa will need to contribute essential quantification data to assist with regional pipeline planning and provide market visibility to suppliers. This will require addressing any hesitance to share sensitive pricing and supplier information, while ensuring seamless interoperability between national and regional data systems.

- **To leverage true economies of scale and ensure fair competition, South Africa must adopt regional regulatory standards and re-evaluate its current import tariffs**. Effective pooled procurement relies on aligned product specifications and the adoption of harmonised medicines regulatory guidelines. Furthermore, South Africa's current tariffs on imported pharmaceutical products will likely need to be adjusted to align with regional agreements and ensure all participating regional suppliers are treated equally.

- **South Africa must coordinate its national procurement structures with regional efforts to prevent overlapping or competitive practices.** Existing national bodies, such as the Directorate of Affordable Medicines, must align their operations with regional initiatives to avoid internal competition. Establishing a central contact point within the country is highly recommended to effectively manage relationships, coordinate requests, and oversee deliveries with the central regional governing body.

- **South Africa needs to prepare for the financial commitments and membership fees necessary to sustain these regional mechanisms.** While specific membership costs are still being discussed, member states are expected to contribute financially to efficiently run the pooled procurement mechanism. For example, the SADC mechanism envisions a fee-based system or membership fee funded by the savings generated from the pooled procurement, which will require member states to allocate specific budgets for this purpose.

- **South Africa must review regional pre-qualification criteria and assess the feasibility of participating in both the APPM and SADC mechanisms concurrently.** The eligibility and selection criteria set by regional mechanisms may differ from existing South African procurement legislation, requiring careful review and alignment. Because both the APPM and SADC mechanisms are in their early stages, South Africa must evaluate specific agreement conditions and potential product overlaps to determine if it is viable to be a member of both mechanisms at the same time.

Assessing South Africa's readiness to participate in regional pooled procurement mechanisms necessitates a thorough examination of the country's health procurement environment and how it aligns with the requirements of open-market pooled procurement systems. As discussed in section 2 above, the legal and regulatory framework governing public procurement in South Africa has evolved over time through multiple legislative and policy instruments, resulting in a framework that is institutionally fragmented. In this context, readiness for participation in cross-border pooled procurement arrangements requires consideration of interconnected legal, regulatory, institutional, regional, and operational dimensions that collectively shape the country's capacity to engage effectively in such mechanisms.

As such, this section is structured around a three-level framework to categorize barriers and opportunities for cross-border procurement. This framework (Table 3 below) provides a structured approach for analysing the factors that may either enable or constrain participation, while also identifying areas in which policy, regulatory, and institutional reforms may be required.

Table 3: Defining the levels of assessment

Level	Definition	Key components
System level	Domestic legal, regulatory, and institutional procurement framework governing how the state purchases goods and services	Resolving legal ambiguities, aligning PPA and NHI Act, and establishing domestic policy positions

Regional level	Multinational, cross-border collaborative structures, treaties, and governance models that South Africa is considering joining	Governance participation, negotiating positions, design-phase leadership, and membership pathway
Operational level	The day-to-day execution, supply chain mechanics, and administrative processes required to operationalise cross-border purchasing effectively	Data systems interoperability, tariff alignment, regulatory harmonisation, supplier eligibility, supply chain logistics

5.1 System level

At this level, South Africa has the opportunity to leverage streamlined governance and centralized purchasing, but must overcome barriers related to legal ambiguities in existing acts, mandatory preferential treatment rules, and unclear institutional roles.

5.1.1 Opportunities for participation

- **Streamlined governance and strategic sourcing -** The Public Procurement Act (2024) consolidates South Africa's highly fragmented public procurement legislation landscape. The Act establishes a Public Procurement Office (PPO) to enforce procurement standards, which is a critical step for standardizing bulk purchasing across government institutions. In addition, Section 24 of the Act enables the development of a framework for strategic procurement, which includes provisions for procuring in other countries, thereby providing a legal pathway for cross-border pooling.

- **Establishment of a centralized purchasing anchor -** The National Health Insurance Act (2023) establishes the Health Products Procurement Unit (HPPU), designed to centralize and coordinate the public procurement of health-related commodities. Having a centralized unit is a vital prerequisite for participating in a regional mechanism, as it allows South Africa to consolidate national demand, align specifications, and manage relationships with regional bodies efficiently.

- **Existing legal precedents for cost reduction -** The Medicines and Related Substances Act (1965) already provide provisions that directly support some of the goals of pooled procurement (cost savings). Section 1(4) permits international tendering, and Section 15C empowers the Minister of Health to allow parallel importation to secure more affordable medical supplies and protect public health. This establishes a favorable legislative precedent aligned with the cost-reduction objectives of regional mechanisms. *However, this should be interpreted within the broader mandate of the Department of Health, where pooled procurement is primarily intended to improve access to essential medicines and strengthen supply security, and not on cost reduction.*

5.1.2 Barriers to participation

- **The absence of explicit provisions in the PFMA Act (1999) regarding its application to internationally sourced contracts -** Amended in 2017, the PFMA Act (1999) regulates financial management in national and provincial governments and holds accounting officers responsible for implementing and maintaining procurement systems and for reporting any instances of irregular expenditure. The Act, however, does not contain provisions specifically addressing the issue of whether, or to what extent, applies to contracts arising from international agreements, international treaties, or which are concluded under provisions financed by multilateral financing institutions. The Procurement Act (2024) once fully enacted will partly address this ambiguity by providing legislation governing procurement of goods and services by procurement entities for goods and services funded either by a donor or by a grant (Section 3 (a); and for procurement in other countries (Section 24(1)). However, sufficient guidelines within the upcoming Procurement

Regulations, being developed to accompany the Procurement Act, should clearly establish the ability and mechanism for joining an international pooled procurement mechanism.

The Procurement Regulations should additionally identify the responsible institution(s) that may participate in an international pooled procurement mechanism. For instance, whether this should be centralized, such as through a lead department or unit, or whether individual departments/units may take this responsibility. There are benefits to centralizing, particularly when participating in international mechanisms as this maintains greater oversight. In the case of joining a health related pooled procurement mechanism, it should also be noted that the Health Products Procurement Unit, established under the National Health Insurance Act (2023) is envisaged to centralize and coordinate the public procurement of health-related commodities and therefore their role must also be considered when determining who shall be responsible for engaging in pooled procurement mechanisms.

- **Lack of clear participation of state-owned enterprises (SOEs) in procurement processes -** Neither the Public Procurement Act (2024) nor PFMA (1999) explicitly address the participation of state-owned enterprises (SOEs) in procurement processes. This omission may impair the rules of fair competition as these SOEs might be seen as having more advantage over other bidders due to their tax exemptions or subsidies. The PPA (2024) refers to the list of entities listed in schedule 1 of the PFMA, and if an SOE is not listed therein, then the PPA Act will not apply. The inclusion of SOEs may discourage private sector participation if this is viewed as creating an unfair advantage. However, the role participation of SOEs in any cross-border procurement is likely to be addressed jointly. As such, clarity will be required on their eligibility to participate to ensure compliance with South African legislation.

- **Impact of legislation around preferential treatment**. Section 17 (1)(a) of the PPA (2024) requires that procuring entities are obligated to reserve bids for specific groups, as long as certain conditions are met. If, however, the prescribed conditions or the required supplier thresholds are not fulfilled, the mandatory set-aside becomes untenable, potentially exposing the institution to legal disputes should it deviate from the prescribed process. It will be important to understand specific supplier eligibility requirements under a regional pooled procurement mechanism as typically any restrictions around eligibility based on a supplier's domicile incorporates all participating countries within the pooled procurement mechanism. As such, it may not be possible to limit participation to bidders from only the purchasing country. In addition, depending upon the specific objectives of the pooled procurement mechanism, there may be no limitations on eligibility. For instance, where the lowest price is the primary objective, all international suppliers may be eligible to participate to ensure maximum competition. By contrast, where the objective is to increase the regional manufacturing base, as stated in the African pooled procurement mechanism, participation by regional bidders may be restricted, which could result in higher prices than those achievable in the international market

- **Unclear role and scope of Health Products Procurement Unit -** Section 38 of the National Health Insurance Act (2024) establishes a Health Products Procurement Unit. It is not entirely clear what the scope of the unit will be. Section 38(2) states that the unit is responsible for the centralized facilitation and coordination of functions related to the public procurement of health-related products, including but not limited to medicines, medical devices and equipment. However, there is ambiguity about what "centralized facilitation", and "coordination" mean. Compounding this lack of clarity is Section 38(3) which tasks the unit with coordinating supply chain management and price negotiations, as well as facilitating procurement, without clearly defining these functions. This uncertainty raises the question of whether the unit will directly procure health-related products. If so, its relationship with service providers remains undefined, especially considering that Section 38(6) states that health service providers are responsible for

procuring products themselves in accordance with the Formulary. This apparent contradiction necessitates clarification to ensure effective and efficient procurement processes within the healthcare system.

To effectively execute its mandate including managing intra-country pooled procurement, the Health Products Procurement Unit will need to develop health procurement guidelines, standard operating procedures including manuals, national health products list, protocols for supply chain management, and contract templates that align with the requirements of the Procurement Act. In addition, should the Health Products Procurement Unit be identified to participate in health-related pooled procurement mechanisms, further expansion of their role, including the activities listed above, will be required to ensure they align the requirements of the regional pooled procurement mechanism.

- **Lack of clarity regarding the National Health Products List -** The exact products that will fall under the Health Products Procurement unit's mandate is also not clear. Section 38(2) of the National Health Insurance Act (2024) states that the unit should facilitate and coordinate procurement of "health-related products, including but not limited to medicines, medical devices and equipment". However, the definition of "health-related product" in Section (1) of the Act creates an inconsistency, as it excludes medicines. This exclusion conflicts with the statement in Section 38 (2), leading to ambiguity as to whether medicines should be considered health-related products.

  In addition, If the national list contains items that are not included in the regional pooled procurement mechanisms, the Health Products Procurement Unit will need to procure these items separately. As such, the unit will be required to consider the regional pooled procurement list, and any subsequent changes, during the annual review of the Formulary (Essential Medicine List, Essential Equipment List, and a list of other health-related products) as provided for by Section 38(5) of the Act and conduct a separate procurement process for these items. This process may increase the complexity of managing separate procurement processes and the likely different terms and conditions for supply under each.

- **Acquisition of services on behalf of the population is still not clear -** Section 39 of the NHI (2024) requires that accreditation be used as a mechanism through which procured services should be acquired. Section 57(b) outlines plans for contracting private providers starting in 2026. It is not, however, clear how these services will be acquired from private providers on behalf of the public. Should services be included within the regional pooled procurement mechanisms, further clarity will be required to understand how the NHI Act will align to the requirements of the mechanism

- **Financial oversight coordination -** While the Procurement Act governs procurement processes, the PFMA demands stringent financial management to prevent irregular expenditure. A gap exists in detailing how these two oversight layers will harmonize to manage the NHI Fund's pooled procurement activities, particularly when integrated with international bodies.

5.2 Regional level

At this level, South Africa's large pharmaceutical market presents an opportunity for strategic leadership and expanding domestic manufacturing, though this is challenged by barriers such as fragmented dispute resolution, sovereignty concerns, and the complexities of participating in regional or continental pooled procurement mechanisms.

5.2.1 Opportunities for participation

- **Strategic leadership in mechanism design -** Both the APPM and the SPPS are currently in early pilot or phased rollout stages. South Africa holds the largest pharmaceutical market in the region, accounting for over half of all medicine sales in Southern Africa (as a region). This market dominance provides South Africa with the economic leverage to assume a leadership role. Rather than adopting existing rules, South Africa should proactively shape the mechanisms' governance frameworks, operational modalities, and supplier pre-qualification criteria to ensure they align with national interests.

- **Leveraging domestic manufacturing capacity** - South Africa is the primary hub for medical production in Southern Africa, boasting at least 122 local pharmaceutical plants and 136 medical device manufacturing companies as of June 2025. Participating in a regional pool provides these domestic firms with expanded access to regional markets. This is particularly advantageous if mechanisms like the APPM implement regional manufacturing preferences to support continental initiatives like the African Vaccine Manufacturing Accelerator (AVMA).

5.2.2 Barriers for participation

- **Fragmented dispute resolution hierarchies -** Cross-border purchasing involves multiple sovereign entities, making contractual disputes inevitable. Currently, there is a lack of harmonization regarding dispute resolution mechanisms specifically for procurement related activities. It is unclear whether a South African domestic appeal process (under the Procurement Act) or regional protocols (such as SADC dispute regulations) would take precedence, creating legal risks.

- **Sovereignty and emergency procurement risk -** The Disaster Management Act (2002) outlines protocols for emergency procurement during a national state of disaster, allowing the government to rapidly acquire essential resources. A barrier exists if the regional mechanism's corporate agreements do not explicitly include emergency exemptions (for example, COVID-19 level emergencies) allowing South Africa to bypass the pool and procure directly from the market when immediate disaster relief is required

- **Simultaneous participation complexity -** Because both the APPM and SPPS are developing concurrently, it remains unclear whether South Africa can legally and practically participate in both mechanisms simultaneously. If there is an overlap in the essential medicines covered by both mechanisms, South Africa will face complex legal decisions regarding which mechanisms corporate agreements and supply conditions take precedence

5.3 Operational level

At this level, there are key opportunities to integrate digital information systems and harmonize regulatory standards, which must be balanced against barriers like IT interoperability gaps, restrictive trade tariffs, and complex budget coordination between the countries involved in pooled procurement mechanisms.

5.3.1 Opportunities for participation

- **Integration of digital information systems -** The SADC and APPM mechanisms rely on coordinated information sharing regarding demand, pricing, and supplier performance. There is a major opportunity to integrate South Africa's National Procurement Information Systems and PPO's ICT platforms with regional shared databases. This interoperability will consolidate demand forecasting, enhance market intelligence visibility for suppliers, and drive significant value for money.

- **Harmonization of regulatory standards -** Pooled procurement allows member states to align on quality standards. Initiatives like the African Medicine Regulatory Harmonization (AMRH) platform and the African Medicines Agency (AMA) provide pathways to streamline Good Manufacturing Practice (GMP) inspections and joint dossier assessments. Adopting these harmonized guidelines will improve the quality of health products entering South Africa and reduce the administrative burden on supply chains.

5.3.2 Barriers to participation

- **Ensuring availability of funds before issuing tenders -** To ensure transparency and accountability in public procurement, PFMA SCM instruction No. 03 of 2021/22 gave mandate to the accounting officers to issue tenders when sufficient budget is available, to avoid possible cancellations at a later stage. This approach will be important when considering participating in a pooled procurement mechanism to avoid cancellation of procurement processes which can discourage supplier's participation in future procurement processes. Further, the mechanism for determining funding availability will need to be coordinated and communicated with the contracting authority of the pooled procurement mechanism to ensure alignment with all contractual payment obligations. It would be preferable to manage this centrally to increase transparency of what has been contracted, spent as well as aide demand planning.

- **Lack of a centralized tracking system for procurement invoicing limits the National Treasury monitoring overall spending, increasing the risk of non-compliance, and procurement-related fraud -** Although government agencies must report late payments to treasuries as stated in the PFMA (1999) and related regulations, the overall extent of the problem remains unclear because the National Treasury lacks the ability to track the total number and value of all invoices processed by all organs of state. Ensuring greater oversight of the expenditure will be required when participating in a regional pooled procurement mechanism, particularly should suppliers refuse to honor future supplies, including to other participating countries due to late or non-payment of invoices. There is also a potential risk with conflicting reporting and financial standards requirements since different regional countries might have varying expenditure reporting standards, frequencies (and fiscal years), and formats compared to the South African requirements. This could create difficulties for health entities in meeting all obligations accurately and efficiently, where these differ significantly. For example, when seeking reimbursements from the fund, Section 39(5) (b) of the NHI Act requires health establishments to submit information, including diagnosis and procedure codes using the prescribed coding systems. These coding stems will have to be harmonized for cross-regional application under a pooled procurement mechanism to ensure payments are made in sufficient time.

- **Restrictive trade tariffs and border mechanics -** South Africa currently imposes trade tariffs on imported pharmaceutical products. Participating in a regional mechanism will require the government to adjust these tariffs (while considering the impact on domestic manufactures) to ensure the equal treatment of regional bidders and to align with SADC-wide tariff harmonization

- **SAHPRA residency requirements -** The South African Health Products Regulatory Authority (SAHPRA) currently mandates that only authorized representatives' resident in South Africa may apply for product registration. This legal residency requirement acts as a direct barrier to cross-border suppliers without a domestic presence, adding prohibitive costs and necessitating mutual recognition agreements to overcome.

- **IT Interoperability and financial tracking gaps -** The absence of a fully integrated, centralized tracking system for procurement invoicing currently limits the National Treasury's ability to

monitor spending. When merged with a regional mechanism, this creates a high risk of conflicting financial reporting standards, as different member states operate on varying expenditure formats, clinical coding systems, and fiscal years.

- **Funding membership and budget coordination -** SPPS and APPM operational structures require sustainable financing, likely through membership fees or fee-for-service models funded by member states' budgets. Coordinating domestic budget approvals with the financial timelines of an international mechanism presents an operational barrier that must be proactively managed.

6 | Recommendations for Alignment and Harmonisation

KEY MESSAGES

- **The National Department of Health (NDoH) must publish a priority product list for pooled procurement that focuses on improving access and supply security**. The list should account for import dependency and existing access gaps and involves mapping South Africa's Essential Medical List against regional lists to guide negotiation mandates.
- **The NDoH should consider constituting the Health Products Procurement Unit (HPPU) using an interim operational team.** Having the Affordable Medicines Directorate as its institutional base, the HPPU can begin regional procurement engagement without having to wait for the full National Health Insurance (NHI) rollout.
- **National Treasury and the NDoH must co-issue a joint regulation to clearly define the legal mandate of the HPPU**. This regulation is necessary to clarify the boundaries between the Public Procurement Office and the HPPU, giving the HPPU the explicit authority to contract on South Africa's behalf in regional and international health product procurement.
- **The National Treasury and the Department of Trade, Industry and Competition (DTIC) must adopt a product-category approach to balance local manufacturing interests with regional**

procurement. They must establish a formal policy that designates "protected categories" to maintain domestic preference and "open categories" where regional competition is permitted for import-dependent products.

- **The South African Health Products Regulatory Authority (SAHPRA) should reform the authorized resident representative requirement to remove barriers for cross-border suppliers.** Because the current legal residency requirement hinders suppliers without a domestic presence, SAHPRA should consider removing it for pooled procurement agreements, introducing tiered compliance, or moving to an electronic registration model.

- **SAHPRA must establish a fast-track registration pathway for products prioritized for pooled procurement.** This expedited review process should establish target timelines, utilize a dedicated case management team, and accept WHO prequalification status as initial evidence of a product's quality.

- **The DTIC must secure a binding emergency procurement exemption in all regional agreements.** This ensures that South Africa retains the right to unilaterally deviate from pooled procurement obligations during a declared national disaster, provided it aligns with the Joint Emergency Preparedness and Response Action Plan.

- **The Department of Science, Technology and Innovation (DSTI) is required to support domestic health manufacturers to innovate and compete regionally.** This involves funding research and development for formulation improvements, supporting technology upgrades for manufacturing compliance, and facilitating technology transfers for Active Pharmaceutical Ingredients.

- **The DSTI must lead the implementation of an integrated data system connecting domestic entities with regional platforms**. This system will enable real-time data sharing among the NDoH, Treasury, and SAHPRA, while also interfacing with regional digital platforms to support multi-year demand planning and contract management.

The recommendations are structured according to the department responsible for implementation. Each departmental sub-section outlines the department's strategic role in South Africa's PPM participation, while also acknowledging cross-cutting dependencies that require collaboration across departments. These recommendations draw heavily on the SAVAX validation and policy dialogue workshop organised by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) on 12 May 2026 for ministerial participants to assess what would be necessary for implementation. As such, they have been prioritised in line with discussions held during the workshop, with additional recommendations included for further consideration.

6.1 The National Department of Health

The NDoH is the lead implementing department for South Africa's participation in regional pooled procurement initiatives for medical products. It serves as the primary point of contact for both the Africa CDC's APPM and the SADC's SPPS. Once established under the NHI Act, theHPPU will function as the central procurement coordination unit.

6.1.1. Identify and publish a priority product list for pooled procurement

First, the NDoH should identify priority products where regional pooled procurement is most likely to improve access and supply security, given that cost savings are not currently among the Department's primary priorities. Selection criteria should include levels of import dependency, existing access gaps, and alignment with APPM/SPPS product coverage. The resulting list should form the basis for regional negotiation mandates and alignment with DTIC industrial policy objectives.

Second, the National Essential Medicines List Committee (NEMLC) should produce a gap analysis mapping South Africa's Essential Medical List (EML) against APPM/SPPS product lists and

specifications. The analysis must identify: (a) products on the EML covered by regional mechanisms with aligned specifications; (b) products where specifications differ - distinguishing clinically significant from administrative differences; (c) products on the regional list not on the EML (access expansion opportunities); and (d) products on the EML not covered by any regional mechanism requiring separate procurement.

6.1.2. Lead the procurement data integration project for regional interoperability

NDoH must provide the procurement data requirements specification for the health information system to interface with regional demand aggregation platforms. Working with Department of Science, Technology and Innovation (DSTI) and Department of Trade, Industry and Competition (DTIC), the NDoH should commission a technical assessment of the architecture required to link health procurement system demand data to the PPO's e-procurement platform with APPM/SPPS data-sharing platforms.

6.1.3. Develop health procurement guidelines, SOPs, and contract templates for HPPU operations

The HPPU (once established) should develop health procurement guidelines; standard operating procedures and manuals; a national health products list; protocols for supply chain management; and contract templates aligned with PPA requirements and compatible with regional mechanism standards. These documents are prerequisites for the HPPU to function as a procurement entity in regional negotiations and for the ongoing coordination between HPPU and health establishments procuring under the Formulary.

6.1.4. Participate actively in APPM and SPPS design phases

South Africa, through representatives from the NDoH, National Treasury and other departments, should continue to participate actively in the design and consultation phases of the APPM and SPPS, in order to assess the implications, opportunities, and institutional requirements associated with future participation. Early engagement in these processes will allow South Africa to shape key governance, procurement, and operational provisions before they are finalized.

Once the necessary institutional arrangements are in place, the HPPU, once formally constituted and mandated, should seek formal participation in APPM and/or SPPS governance structures. This will require: (a) formal government-to-government communication with the AU and SADC Secretariats confirming South Africa's intention to participate; (b) designation of HPPU representatives to participate in governance and technical working group meetings; and (c) development of a position paper(jointly with National Treasury and DTIC) setting out South Africa's interests and parameters on issues such as domestic preference, emergency exemptions, and dispute resolution.

6.1.5. Constitute the HPPU with a core operational interim team, using Affordable Medicines Directorate (AMD) as the interim institutional base.

NDOH should consider operationalizing HPPU, without waiting for the full NHI rollout. This can be done administratively by: (a) designating AMD as the interim HPPU operational base; (b) appointing an acting HPPU Head with a mandate for regional procurement engagement; (c) seconding a minimum core team of procurement specialists, health economists, and legal counsel with international trade experience; and (d) issuing interim operating procedures.

This would ensure continuity between current engagement processes and the future institutional structure that will ultimately assume responsibility. The NDoH could further position the interim arrangement as preparatory institutional work, rather than ad hoc representation by individual departments.

6.2 The National Treasury

National Treasury's role is foundational. As the custodian of the PFMA, the architect of the PPA, the host of the Public Procurement Office, and the co-custodian of the NHI Fund's financial governance, no legal basis for participation can be established without Treasury's active engagement. Treasury is also the only department with the cross-cutting authority and institutional mandate to hold all other departments accountable.

6.2.1 Co-issue a joint regulation with NDoH resolving the PPO-HPPU mandate boundary

Produce a jointly gazetted regulation, under the enabling provisions of both the PPA and the NHI Act defining: (a) HPPU's authority to contract on behalf of South Africa in regional procurement mechanisms for health products; (b) its PFMA status and accountability to Parliament; (c) its relationship with the PPO for health-related procurement oversight; and (d) the dispute resolution mechanism between the two bodies.

National Treasury, working with NDoH, must also ensure that the draft General Public Procurement Regulations (2026): (a) authorise participation in international health-related pooled procurement mechanisms; (b) designate the HPPU as the responsible institution for health-related cross-border procurement; and (c) specify the financial controls, reporting requirements, and accountability mechanisms for cross-border contracts. Failure to act during this drafting window means a further amendment process will be required after enactment.

6.2.2 Align domestic procurement policies with local manufacturing through a product-category approach

Working with DTIC, prepare a formal government policy position distinguishing: (a) protected categories where domestic preference requirements are retained and pooled procurement is not applied; and (b) open categories where regional competition is permitted and domestic preference thresholds are waived or adjusted. This replaces the current blanket approach with a calibrated, evidence-based system that protects strategic domestic manufacturing interests while enabling regional procurement where South Africa has import dependency.

6.2.3 Design a sustainable financing plan for PPM (beyond donor financing)

Commission a financing options paper addressing: (a) options for a domestic budget line for HPPU operationalisation and IT integration; (b) the mechanism for ring-fencing a portion of realised PPM savings for mechanism operating costs; and (c) Co-financing options for IT infrastructure investment. The goal is to ensure institutional continuity regardless of external funding availability.

6.2.4 Monitor implementation progress to guide the time and scope of participation

Once the domestic framework is unified and regional engagement begins, the National Treasury must maintain a structured assessment of whether conditions are sufficient to justify deeper participation and at what product scope. This assessment serves as the governance mechanism that prevents South Africa from either committing prematurely or deferring indefinitely.

6.3 South African Health Products Regulatory Authority (SAHPRA)

SAHPRA's regulatory requirements may create barriers to participation in regional pooled procurement initiatives. Negotiations on Mutual Recognition Agreements (MRAs) with SADC regulatory counterparts are also likely to be protracted. For this reason, SAHPRA should prioritize the regulatory harmonisation measures required to support participation and initiate the necessary processes as early as requested by the NDoH, DTIC and National Treasury.

6.3.1 Assess options for reforming the authorised resident representative requirement

SAHPRA should undertake a legal and risk assessment of options for reforming the current residency requirement. Options to assess include: (a) full removal for products sourced through a government-to-government pooled procurement agreement; (b) tiered compliance based on product risk category; and (c) replacement with an electronic registration model under an MRA framework.

6.3.2 Establish an expedited registration pathway for pooled procurement priority products

Create a fast-track review process, analogous to the existing permit requirements, for products on the agreed PPM priority list. Key design requirements: (a) a timeline-review target from complete dossier submission; (b) dossier requirements that accept WHO prequalification status as prima facie evidence of quality; (c) a dedicated SAHPRA case management team for pooled procurement products; and (d) a published list of products eligible for the fast-track pathway, aligned with the NDoH priority product list.

6.3.3 Make the SAHPRA registration database interoperable with NHIS (procurement data) and PPO platforms

Working with DSTI and NDoH, specify the technical requirements for SAHPRA's product registration database to be query-able by the NDOH's health system and by the PPO's e-procurement system, enabling automated verification of product registration status at the point of procurement. This interoperability specification should be included in the DSTI-led data architecture working group as a core output.

6.3.4 Actively participate in AMA Treaty governance and the AMRH regional harmonisation programme

Following Parliament's ratification of the AMA Treaty, SAHPRA must engage the AMA governance structures as an active technical participant (not merely as a signatory). SAHPRA's regulatory and institutional capacity make it a natural leader in the AMRH programme. Active participation accelerates continental regulatory harmonisation, which is the structural foundation for sustainable pooled procurement across Africa. This is however dependent on whether South Africa would ultimately use APPM.

6.3.5 Commission a feasibility study on Mutual Recognition Agreements (MRAs) with SADC/AMA regulatory counterparts

SAHPRA must commission a feasibility study assessing: (a) which SADC NMRAs have regulatory frameworks sufficiently equivalent to SAHPRA's standards to support a mutual recognition arrangement; (b) design options for an MRA , full mutual recognition, reliance (accepting another authority's assessment without repeating it), or abridged review; (c) the legal basis for an MRA under the SADC Protocol on Health and the AMA Treaty framework; and (d) the risks and safeguards required.

6.4 Department of Trade, Industry and Competition (DTIC)

DTIC's current policy framework, including domestic preference, local content requirements, and B-BBEE, sits in tension with the principles of open regional competition. DTIC will need to make an evidence-based determination on where protection is maintained and where regional competition is enabled. Absence of a clear position effectively preserves the status quo, which would limit South Africa's participation. At the same time, DTIC can play an enabling role, as the APPM manufacturing preference agenda offers opportunities for South African pharmaceutical producers to access regional markets with appropriate policy support.

6.4.1 Develop a local Active Pharmaceutical Ingredients (API) production enablement programme

Design a targeted incentive package for domestic API manufacturing, drawing on: Industrial Development Corporation (IDC) financing instruments; Special Economic Zones investment support for pharmaceutical API facilities; Industrial Policy Action Plan (IPAP) alignment for pharmaceutical manufacturing; and R&D tax incentives for API development. This programme should be a parallel workstream to PPM participation, given South Africa's import vulnerability in APIs is a national security issue regardless of PPM decisions. The programme design should explicitly target products on the NDoH priority product list.

It will also reduce dependence on imported pharmaceutical products, particularly from India and China, and may support EU-South Africa trade negotiations on exports once domestic capacity to manufacture specific medical products has been established.

6.4.2 Commission an economic impact assessment on local pharmaceutical manufacturing under PPM scenarios

Commission an independent economic impact assessment modelling the employment, revenue, and industrial development impact of three PPM participation scenarios: (a) no participation; (b) limited participation with manufacturing preference; (c) full participation with open competition. The assessment must include sector-specific analysis for pharmaceutical manufacturers, medical device manufacturers, and API producers. This could also form part of the evidence base for the policy position on tariff adjustment pathway below (6.4.3).

6.4.3 Design a phased pharmaceutical tariff adjustment pathway

Working with the National Treasury, model a time-bound tariff reduction pathway for pharmaceutical products covered by regional pooled mechanisms. The pathway must: (a) be phased over an agreed-upon timeline (3–5 years rather than immediate) necessary to manage transition risk; (b) include compensatory support (IDC access, skills development, supply chain upgrading) for manufacturers affected by tariff reduction; (c) be product-specific rather than sector-wide; and (d) be conditional on the specific products being included in an active pooled procurement contract. A blanket tariff reduction unlinked to PPM participation would harm manufacturers without delivering the procurement benefit.

6.4.4 Produce an industrial policy reconciliation document aligning Industrial Policy Action Plan (IPAP) with regional PPM obligations

Produce a formal reconciliation document mapping existing industrial policy commitment under IPAP against the obligations of APPM and SPPS membership. Identify: (a) provisions in IPAP compatible with PPM obligations; (b) provisions requiring amendment or time-limited waiver; and (c) new IPAP provisions that should be added to capture the industrial development opportunity that regional market access creates.

6.4.5 Develop a support package for South African manufacturers to meet regional supplier eligibility criteria

Design a support programme enabling domestic health manufacturers to meet APPM and SPPS supplier eligibility requirements, including: GMP compliance assistance through the Council for Scientific and Industrial Research (CSIR) and the Technology Innovation Agency (TIA); certification cost subsidies for WHO prequalification; scale-up financing for manufacturers seeking to serve regional volumes; and supply chain development support. The APPM creates a regional market for South Africa manufacturers that did not previously exist, and DTIC must ensure South Africa manufacturers are positioned to access it.

6.4.6 Produce an internal policy position on domestic preference vs. regional open competition by product category

As highlighted under 6.2.2 (National Treasury), the internal policy position should be jointly developed with the National Treasury. The DTIC and National Treasury must resolve, through a formal policy document, which health product categories receive full domestic preference protection, and which are designated as open to regional competition. The position paper must: (a) draw on the NDoH priority product list once available; (b) assess which products South Africa has genuine domestic manufacturing capacity to supply at competitive prices; (c) identify products where South Africa is structurally import-dependent and where regional competition will reduce costs without displacing domestic production; and (d) propose the specific policy instruments (waiver, gazette notice, ministerial designation) required to give effect to the category distinction.

6.4.7 Harmonise domestic and regional dispute resolution frameworks

Establish a formal legal hierarchy for health procurement disputes involving regional mechanisms. The hierarchy must specify: (a) which disputes are subject to South African domestic law exclusively; (b) which are subject to regional mechanism rules; and (c) which require a joint dispute resolution process. The hierarchy must be encoded in any agreement South Africa signs with the APPM or SPPS and must be compatible with the provisions of the PPA, NHI Act, and PFMA. National Treasury, NDoH, and the Department of Justice must jointly lead the legal design.

6.4.8 Negotiate a binding emergency procurement exemption in all regional agreements

Every agreement South Africa signs with the APPM or SPPS must contain an explicit clause allowing South Africa to deviate unilaterally from pooled procurement obligations when a national disaster is declared under the Disaster Management Act. This clause must be: (a) binding, not subject to regional mechanism override; (b) time-limited, operative only for the duration of the declared disaster; (c) subject to notification to the regional mechanism rather than prior approval; and (d) aligned with the Joint Emergency Preparedness and Response Action Plan (JEAP) provisions under the Africa CDC-WHO framework. Other government agencies - Department of International Relations and Cooperation (DIRCO), NDoH, and National Treasury must present a unified position on this.

6.5 Department of Science, Technology and Innovation (DSTI)

The DSTI should lead the inter-departmental data architecture work required to enable South Africa's contribution of demand signals to regional platforms. It also plays a central role in developing the innovation support infrastructure that positions South African manufacturers to compete in and supply regional markets. DSTI is the appropriate lead for this function, given its cross-government digital mandate and technical capacity, which are not equally available within the NDoH and National Treasury.

6.5.1 Support South Africa health manufacturers to innovate and compete in regional pooled procurement markets

Deploy existing DSTI instruments (Technology Innovation Agency, Council for Scientific and Industrial Research (CSIR) and Small Enterprise Development Agency) to fund R&D for: (a) pharmaceutical formulation improvement for products on the NDoH priority list; (b) GMP compliance technology upgrades at domestic manufacturing facilities; and (c) technology transfer for API production using CSIR's pharmaceutical chemistry capabilities. DSTI's role is primarily on technology and innovation, financing for scale-up should be DTIC/IDC's role. The two departments must work jointly to ensure South Africa's manufacturers receive both technological support and commercial financing.

6.5.2 Build demand forecasting and quantification analytical capability in NDoH/HPPU

Deploy data science and health informatics resources to build a demand forecasting capability within the HPPU. Without reliable multi-year demand projections, South Africa cannot negotiate credibly, and regional suppliers cannot plan production. The forecasting model must draw on South Africa's consumption data, demographic projections, and epidemiological trend data.

6.5.3 Implement the integrated data system connecting NHIS (procurement data), PPO, SAHPRA, and regional platforms

Lead the procurement and implementation of the integrated system. The system must: (a) enable real-time data sharing between NDoH, Treasury, and SAHPRA; (b) interface with the APPM's digital platform and SPPS data systems; (c) support multi-year demand planning and contract management; and (d) comply with data governance standards required for cross-border data sharing under SADC data protection frameworks.

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