



Private sector HIVSS landscape

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Acknowledgements

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Introduction

HIVSS in the private sector

- ∂ Pharmacies have been cited as convenient and discrete outlets to acquire HIVSS, and are seen as stocking high-quality products and offering test use support (if needed).
- ∂ Regulatory barriers have slowed market development;
- ∂ In some countries, a substantial gap exists between average willingness to pay and current market prices;
- ∂ Diversity in product preferences mean that access to both oral-fluid and blood-based HIVSS should be supported in the private

Purpose of South Africa Private Sector Landscape

- ∂ Determine the perceptions and practices of key stakeholders towards HIV Self-Testing Kits (HIVSS) in SA private sector market.
- ∂ Identify constraints on the SA private sector markets ability to offer high quality, affordable HIVSS to contribute to the first 90 target
- ∂ Develop recommendations to accelerate the development of a sustainable market

Methodology

Methodology

Desk review. Structured in-depth interviews and questionnaires with key market players

Sample

15 key thought leaders

Data collection

Tool developed to collect qualitative and quantitative data

Data analysis

Coded and grouped into similar themes

TYPE	ORGANIZATION INTERVIEWED
Policy Makers	SA Pharmacy Council (SAPC), HIV Clinicians Society, South African Health Products Regulatory Authority (SAHPRA)
Associations	Independent Community Pharmacy Association (ICPA), South African Medical Device Association (SAMED), South African Business Coalition Against HIV/AIDS (SABCOHA)
Medical Aid Schemes	Discovery, Metropolitan Health
NGOs	TB HIV Care, Desmond Tutu HIV Foundation (DTHF)
Distributors	Mylan, Alpha Pharm
Retail Pharmacies	Clicks, Dischem, Spar





Background on Private Sector

A two-tiered healthcare system

Key indicators (2015)	
Population	53.7 million
Per capita GDP	\$5,784
Health expenditure	\$23 billion
Per capita health expenditure	\$593
Government % of THE	48.4%
Donor % of THE	1.8%
Private sector % of THE	46.8%
Out of Pocket as a % of THE	7.1%

PRIVATE SECTOR

PUBLIC SECTOR

About 16% of the population (7 million people) purchase private healthcare



Nevertheless, private healthcare expenditure accounts for half of total health expenditure



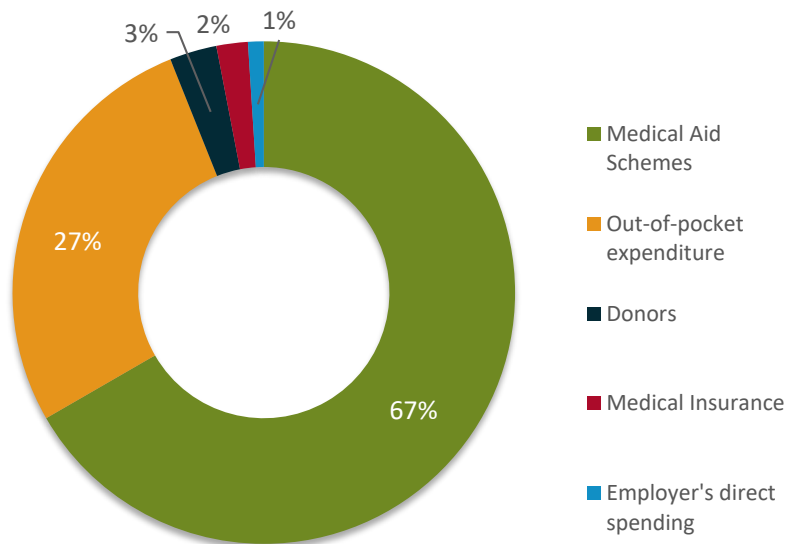
And more than 86% of expenditure on pharmaceuticals



Sources:
 South Africa Health Financing Profile. Washington DC, Health Policy Project. 2016.
 A review of the South African Pharmaceutical landscape. ImpactRx (an IMS Health Company), November 2015

Private health care funding

PRIVATE HEALTHCARE FUNDING BY SOURCE 2015

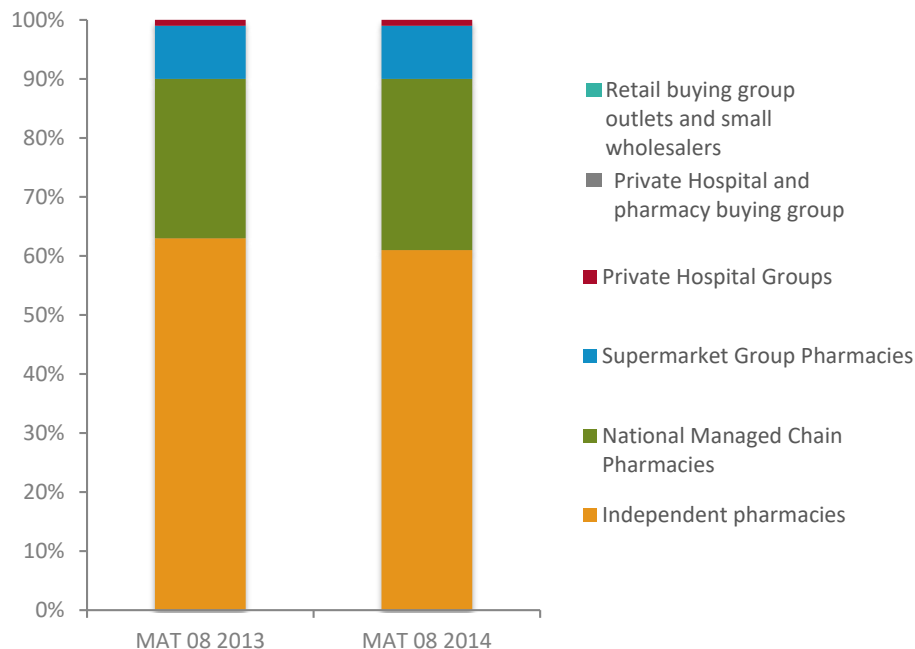


- ▶ Private healthcare funding largely consists of funding through 92 medical aid schemes and out-of-pocket expenditure
- ▶ Medical aid schemes manage contributions and process payments for services from registered healthcare providers including retail pharmacies and medical doctors
- ▶ Cover core services from the prescribed Minimum Benefit Package (MBP). Each scheme covers different services but all are mandated to cover the services from the MBP.

Source:
SHOPS Project. 2015. South Africa Private Health Sector Assessment. Bethesda, MD:
Strengthening Health Outcomes through the Private Sector Project, Abt Associates.

Retail pharmacies in South Africa

TRADE CHANNEL BREAKDOWN



- ▶ More than 3,300 community pharmacies with sales of approx. US\$3.2 billion in pharmaceutical sales in 2017
- ▶ Independent pharmacies account for ~ 60% of pharmaceutical volume and value
- ▶ National managed chains, including Clicks, Dischem, and Alpha Pharma, account approximately 30% of the market
- ▶ Retail supermarkets account for just under 10% of the market but is the fastest growing segment

Retail pharmacies have ...

PHARMACIES	OUTLETS	SCALE
Clicks	>500	Leading corporate pharmacy in South Africa with 500 outlets and annual turnover of more than 24 170 Rm (US\$1.77 billion)
Dis-chem	108 + 525 independent	Large corporate pharmacy with 108 dischem stores and 525 independent pharmacies with annual turnover of more than 17 000 Rm (US\$1.24 billion)
Alpha Pharm	920 community pharmacies – 420 branded	Alpha Pharm operates as a network of independent pharmacies, dispensaries, community pharmacies and big super stores. Private company owned by Swiss investment firm. Also serves as wholesaler and distributor.
Independent pharmacies	~1,100	Independent Community Pharmacy Association (ICPA) represents more than 1,100 pharmacies
Pick'n Pay	1417	Pick n Pay is a multi-format, multi-channel retailer. The middle-income South African consumer, makes up the largest portion of our customer base. Annual turnover of 81 000 Rm (US\$5.9 billion)
ShopRite	2000	Largest FMCG retail operation in Africa - 1,855 corporate and 359 franchise stores in 15 countries. Turnover of 130 Rm (US\$9.5 billion). Served 1 Billion customers/year.
SPAR	2000+ stores in Southern Africa	Turnover of more than 50 000Rm (US\$2.3 billion) in South Africa.





Key Findings and Recommendations

HIVSS in the private sector is moving forward

BioSure and Atomo have launched private sector sales while bioLytical, Chembio and Orasure are taking a wait-and-see approach

	Atomo HIV Self-test	BioSure HIV Self-test	INSTI HIV Self-test	Sure Check HIV Self-test	OraQuick HIV Self-test
Manufacturer	Atomo	BioSure	BioLytical	Chembio	Oraquick
Specimen	Blood	Blood	Blood	Blood	Oral fluid
Regulatory Status	ERP-D III CE marked	ERP-D III CE marked	WHO Pre-qualified	ERP-D III CE marked	WHO Pre-qualified
Launched in private sector	✓	✓			
Outlets	Pick n Pay, Dishem, Alpha, Clicks, Independent pharmacies	Dischem, Spar, Pick n Pay			
Retail Price	R139-199 US\$10.35 – 14.82*	R150-180 US\$11.17 – 13.40			

Pharmacies are stocking HIVSS and POC tests

Point-of-care tests (professional use tests) are sold alongside HIVSS at lower prices and with little differentiation in packaging

		Pick n Pay	Dischem	Alpha	Clicks	Independent pharmacies
HIVSS	Atomo i-test	R139 (US\$10.32) (30 pharm.)	R146 (US\$10.84) (170 pharm.)	R190 (U\$14.17) (900pharm.)	R199 (U\$14.77) (470 pharm)	R169 (US\$12.54)
	BioSure HIV self-test		R157 (US\$ 11.65) (250 pharm.)			
POC (Professional use tests)	U-test			R45 (US\$3.34)		R45 (US\$3.34)
	Biosmart			R89 (US\$6.60)		R89 (US\$6.60)
	HIV I Know			R30 (US\$2.23)		R30 (US\$2.23)
	HIV test kit 1 & 2			R70 (US\$5.19)		R70 (US\$5.19)





- ▶ Point-of-care tests (professional use tests) are sold alongside HIV self-tests at lower prices and with little differentiation in packaging.
- ▶ In June 2018, AlphaPharm was also selling a white label version of their own HIVSS

Early sales

From November 2017 – February 2018, total sales of HIV test kits (HIVSS and POC tests) sold through pharmacies amounted to less than 15,000 units

Total sales of HIV test kits including both HIVSS and PoC tests

	NOV 2017	DEC 2017	JAN 2018	FEB 2018	TOTAL TO DATE
CORPORATE PHARMACY	1000	2500	4000	5000	12500
INDEPENDENT PHARMACY	120	480	600	980	2180
TOTAL	1120	2980	4600	5980	14680

- ▶ Blood-based products are the only products sold to date
- ▶ Some online sales have been initiated, but at low volumes
- ▶ Retailers noted that no demand generation activities had been launched



Pharmacy and retail strengths



- ▶ **Sales have started:** Leading pharmacy and retail chains have begun to sell CE-approved HIVSS.
- ▶ **Easy access:** HIVSS are generally kept in the front of shops and customers can take them off the shelves.
- ▶ **Vast reach and scale:** With more than 3,300 outlets and \$3.2 billion in sales, South African pharmacies can deliver scale. Retail chains such as Pick 'n Pay, ShopRite and Spar have pan-African presence

Pharmacy and retail weaknesses



- ▶ **Sales of POC products:** Low priced POC tests continue to be sold alongside HIVSS at AlphaPharm and at independent pharmacies despite 2017 SAPC board notice
- ▶ **Limited uptake in independent community pharmacies**
- ▶ **Limited to no demand creation activities:** No consumer awareness materials available in-person or online
- ▶ **Staff training and promotional materials:** Distributors requested manufacturers send representatives to train the pharmacy staff and will wait for manufactures to develop consumer and promotional materials
- ▶ **Lack of oral fluid products:** Orasure HIVSS kit only available for private sector purchase through internet sales where it is priced extremely high – R1655 (US\$ 122)
- ▶ **Unclear post marketing surveillance systems**
- ▶ **High prices**

Pharmacy and retail opportunities



Reduce the high cost of products in the private sector

- ▶ **Remove VAT:** South Africa taxes HIVSS at 15% VAT.
- ▶ **Volume discounts:** Exempt HIVSS from Sections 18A and 18B of the Medicines and Related Substances Act which prohibits Bonusing, Rebates and Incentive Schemes to promote volume discounts.

Remove POC tests from the market

- ▶ Advocate with AlphaPharm, the Independent Community Pharmacy Association (ICPA) and the South African Pharmacy Council to remove POC tests.

Engage in demand creation and training

- ▶ Public sector programs such as STAR could be leveraged to create demand at the category level. Teams can also share consumer research and promotional materials.

Establish systems to monitor private sector sales

- ▶ **Explore opportunities with Nielsen and/or IMS Health**

Medical Aid Schemes Strengths



- ▶ **Reach:** Two medical scheme administrators, Discovery and Metropolitan Health, provide administration and managed care to over 5.3M beneficiaries.
- ▶ **Capacity:** Manage contribution payments for various medical aids and process payments for services from registered healthcare providers such as retail pharmacies and medical doctors. The health technology assessment units are well positioned to evaluate HIVSS and its impact on health system efficiency.
- ▶ **Follow public sector product guidelines:** Medical aid administrators reported that they comply with and support the published regulations, policies and guidelines (World Health Organization, SA National Department of Health and South African Pharmacy Council)

Medical Aid Schemes



Weaknesses

- ▶ **On Hold:** Medical aid schemes reported that they are waiting for updated Department of Health Guidelines and product selection criteria before moving forward with their evaluation of HIVSS.
- ▶ **Concerns on lack of linkages:** Administrators were aware of WHO guidance, however, they expressed concerns about linkages to care and linkages to counselling programs.



Potential Opportunities

- ▶ **Advocacy and dissemination:** Establish a workplace task team to ensure HIV Self testing is a Prescribed Minimum Benefit in relation to the medical aid insurance reimbursement
- ▶ **Mobilize movement on linkages in the private sector:** Develop a multi-sectoral linkage to care task team to develop implementation guidance. Should include NDOH, SAPC, and Council of Medical Schemes.
- ▶ **Engagement from blood-based manufacturers:** Orasure is not targeting the private sector markets like blood-based manufacturers BioSure and Atomo, yet is the only company with a product that is consistent with public sector guidelines.

Recommendations



National Department of Health

- ▶ Support SAHPRA and ICPA to remove POC tests from the shelves of independent pharmacies
- ▶ Fast-track SAHPRA regulatory processes to enable additional products to be registered
- ▶ Ensure that adverse events and medical device vigilance processes are well communicated by all stakeholders
- ▶ Ensure that HIVSS is a Prescribed Minimum Benefit for medical aid schemes and the NHI
- ▶ Remove VAT
- ▶ Include mobilization of private sector within the scope of the Technical Working Group
- ▶ To facilitate linkages, NDoH could mandate that a standardized care card bearing its logo be distributed with all products.

Recommendations



Public sector implementers

- ▶ Disseminate findings on linkages to medical aid administrators
- ▶ Align promotional activities to promote HIVSS at the category level and reference pharmacies as a place where HIVSS can be obtained.
- ▶ Share promotional materials with private sector players

Manufacturers

- ▶ Engage SABCOHA (South Africa Business Coalition of Health and AIDS) and Unions to explore workplace distribution models
- ▶ Engage private sector provider channels through the HIV Clinicians Society
- ▶ Ensure effective systems of post market surveillance

Thank you

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Discussion

- ▣ Is subsidy needed to achieve public health impact through the private sector? What evidence would be needed to support this investment?
- ▣ How can we leverage existing investments to help overcome some of the challenges in the private sector?
- ▣ Could online channels be a mechanism to target high risk testers? How can these be tested?

Possible distribution models

1. Retail pharmacies and outlets
2. Open access distribution with vouchers
3. Workplace programs
4. Private sector clinics

The HIV epidemic in South Africa



7.1 million people living with HIV

63% of people living with HIV are female

270,000 new HIV infections

110,000 AIDS-related deaths

86% of adults aware of their status

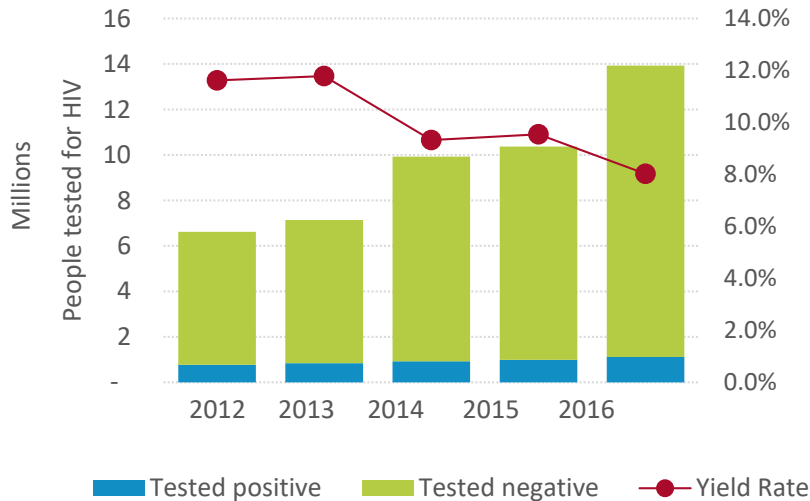
56% of adults antiretroviral treatment

Source: UNAIDS, available from:
<http://www.unaids.org/en/regionscountries/countries/southafrica>

Testing volumes increasing to achieve first 90 target

...but declining yield rates increase the number of tests need to identify positive cases

HIV TESTS AND YIELD, SOUTH AFRICA 2012-2016



- ▶ Yield rates are declining as more people living with HIV are identified and linked to treatment
- ▶ As a result, maintaining progress requires better targeting and/or increases in testing volumes

Source: PEPFAR

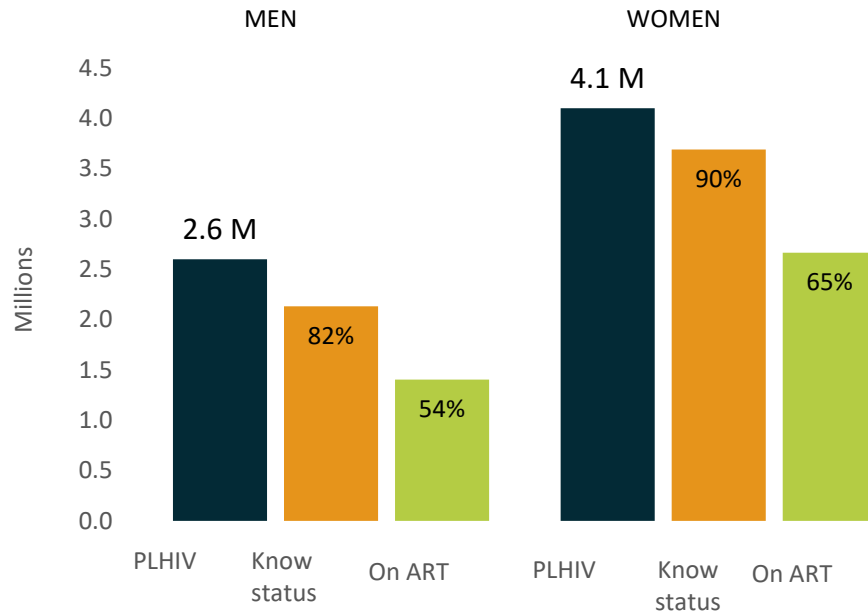


UNAIDS-PSI
HIV SELF-TESTING AFRICA



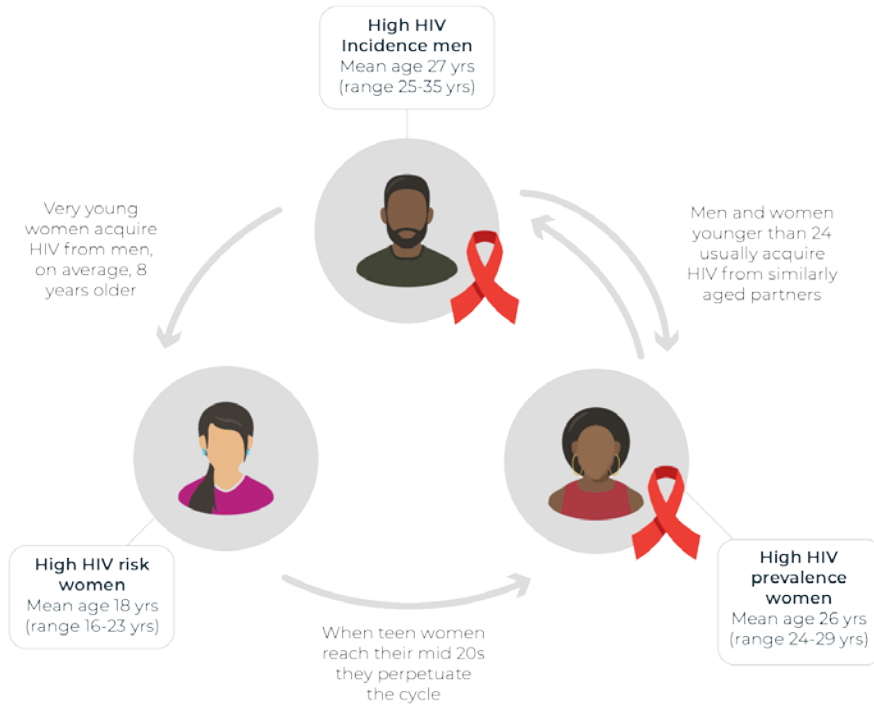
Progress in reaching men lags

SOUTH AFRICA HIV TREATMENT CASCADE, 2016



- ▶ Men are less likely to take an HIV test. In 2016 an estimated 45% of men tested for HIV compared to 59% of women.
- ▶ Fewer South African men living with HIV start and remain on HIV treatment, and men are more likely to die of AIDS- related causes.

The cycle of new infections



- ▶ High risk men are a major driver of the high incidence rate amongst adolescent girls and young women (aged 15-24). This group accounted for 30% of all new HIV infections in 2016 despite being only 12% of the adult population.
- ▶ In 2016, an estimated 104,000 adult men acquired HIV, representing 39% of adult infections.
- ▶ Modelling suggests that almost one in every four boys (23%) currently aged 15 will acquire HIV before they reach 60.

Testing rates amongst youth also lower


Age groups	MEN			WOMEN		
	Total surveyed	Proportion ever tested for HIV	Proportion tested in the past 12 months and received the results of the past test	Total surveyed	Proportion ever tested for HIV	Proportion tested in the past 12 months and received the results of the past test
15-19	647	46.5%	28.7%	1427	50.5%	38.4%
20-24	588	70.6%	49.3%	1415	85.5%	66.7%
25-29	506	78.5%	52.8%	1444	92.8%	68.4%
30-39	845	77.8%	48.0%	2406	92.9%	63.2%
40-49	616	82.0%	45.3%	1823	88.0%	54.0%
50-59	416	75.9%	40.9%	0	-	-
15-24	1235	58.0%	38.5%	2842	68.1%	52.5%
15-49	3202	71.1%	44.6%	8515	83.5%	58.5%

Source: A snapshot of men and HIV in South Africa. UNAIDS, Geneva 2017.



Industry Associations

- ▶ **South Africa Business Coalition of Health and AIDS (SABCOHA):** Member-based organization that aims to coordinate a private sector workplace response to HIV/AIDS. Consisting of banking, mining, construction, occupational health, and other types of companies, SABCOHA supports Bizwell project which could provide an entry point for workplace testing in small and medium enterprises such as taxi drivers, builders and formal and informal traders. Have not yet considered HIVSS.
- ▶ **HIV Clinicians Society:** Membership based organization consisting of 3,000 healthcare workers (1,800 in the private sector). Published own HIVSS guidelines in May 2017, and have held roadshows to support HIVSS. However, demand creation activities have been limited and awareness is low amongst membership.
- ▶ **South African Medical Technology Industry Association:** Represents the interests of 160+ companies. Recommends changes to the Bonusing, Rebates and Incentive Schemes for HIVSS to enable volume discounts.

A woman with short dark hair and glasses, wearing a white lab coat, is smiling and holding a HIV test kit and a brochure. The brochure is titled 'HIVSS' and features a diagram of the testing process. The background is slightly blurred, showing other people in a clinical setting.

HIVSS included in strategy to reach first 90 target in South Africa

Much progress has been made since the official launch of HIVSS

- ▶ Retail pharmacies allowed to sell home-use HIV test kits
- ▶ Department of Health is drafting HIVSS guidelines
- ▶ National Strategic Plan for HIV, Tuberculosis and Sexually Transmitted Infections 2017-2022 emphasizes high yield HIV testing and leaving no one behind
- ▶ Unitaid-funded HIVSS Africa Initiative (STAR) expanding to South Africa's public sector

Regulation

- ▶ South African Pharmacy Council (SAPC) regulates pharmacists, pharmacy support personnel and pharmacy premises in South Africa. Removed ban on HIVSS in November 2016 and established minimum standards in November 2017. Standards lack clarity on products
- ▶ The South African Health Products Regulatory Authority (SAHPRA) formed in 2017. All encompassing regulatory body responsible for medical devices. Requiring that all manufacturers and distributors of HIVSS be licensed by August 2017 or submit application for licensing. Challenges include:
 - No funding for enforcement
 - Struggling with removal of POC kits
 - Has not fast tracked the approval of HIVSS kits which will be required for Medical Aid Schemes
- ▶ General Regulations Relating to Bonusing, Rebates and Incentive Schemes Section 18A and 18B of the Medicines and Related Substances Act 101 of 1965 **prohibits volume discounts**, bonuses, rebates, free samples