



# Annual Report 2018/19



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Health Portfolio committee presentation 15 October 2019

# NEW *Beginnings*



Starting over can be challenging, but also it can be a great opportunity to do things differently.

*Catherine Pulsifer*

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# Introducing SAHPRA

## New Kid on the block: Schedule 3A Public Entity

With a regulatory scope that has expanded to include all medicines, medical devices, radiation emitting devices and radioactive nuclides



Globally accepted well-functioning drug regulatory authority as essential component of an effective health system

Aligned with global trends

Aim to be a transparent and effective regulator, sensitive to the context in which it operates whilst being independent of public, commercial and political pressures

Through a patient-centred approach, SAHPRA aims to safeguard the health and well-being of all who live in South Africa, both human and animal

A key role to play in achieving universal health coverage and in the planning for National Health Insurance (NHI). Ensuring equitable access to safe, effective and quality medicines and health products is an essential pillar to a revamped and reinvigorated health system.

## VISION

To strive towards excellence in health product regulation with the aim of promoting and protecting human and animal health in South Africa, and being recognised and respected both nationally and globally as a leading and exemplary health product regulator.

## MISSION

To safeguard the health and wellbeing of all who live in South Africa and to support human and animal health through scientific and ethical regulation of medicines, medical devices, radiation emitting devices and radioactive nuclides.

## VALUES

SAHPRA has identified the following values as the principles that will underpin the policies, procedures, code of conduct and culture of the organisation:

Care; Ethical conduct; Unity of purpose; Service excellence; Transformation; Innovation; Integrity

# Strategic Outcome-oriented Goals

## Goal 1: Publicly demonstrate responsiveness and accountability as an effective and efficient high-performance organisation

SAHPRA places prominence on good management, from well-considered planning to effective performance measurement.

SAHPRA aims to be an effective and efficient high performing organisation that is responsive and publicly accountable.

Achievement of this goal rests to a large extent on sound financial and human resources management and the effective use of information technology to support business processes and the interface with stakeholders.

## Goal 2: Timeous regulatory decisions taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance

The Authority strives to make timeous regulatory decisions based on defined standards for quality, safety, efficacy and performance.

## Goal 3: Re-evaluate and monitor medicines and medical devices

The Authority endeavours to establish a framework to ensure that registered products are periodically re-evaluated in accordance with the defined standards of quality, safety, efficacy and performance.

# Strategic Outcome-oriented Goals

**Goal 4: Investigate, monitor, analyse and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance**

The Authority seeks to ensure that evidence of existing and new adverse events, interactions, signals emerging from post-marketing surveillance and vigilance are being solicited, investigated, monitored, analysed and acted upon, and that supportive national and global partnerships are established.

**Goal 5: Ensure regulatory compliance through a process of active inspections and investigations**

The Authority undertakes to inspect and investigate establishments and permit holders in accordance with the defined guidelines and standards.

**Goal 6: Evaluate clinical trial protocols in accordance with defined standards**

The Authority seeks to safeguard the public and data integrity by evaluating clinical trials in accordance with the defined standards.

# Strategic Outcome-oriented Goals

## **Goal 7: Evaluate the applications for sale of unregistered health products in accordance with defined standards**

The Authority endeavours to ensure that unregistered health product applications are evaluated in accordance with defined standards of safety, efficacy and quality for unregistered health products.

## **Goal 8: Establish and strengthen collaborative initiatives with any other regulatory authorities or institutions in order to achieve the objectives of the Medicines Act**

The Authority seeks to liaise with any other regulatory authority or institution with a view to exchange information with and receive information from any such authority or institution in respect of (i) matters of common interest, or (ii) a specific investigation, and to enter into agreements of collaboration with any other regulatory authority or relevant organisation.

## **Goal 9: SAHPRA is capacitated by adequate, competent and motivated human capital**

A functional SAHPRA with a budget and personnel to implement the Authority's mandate effectively is phased in and will be fully operational by 2022.

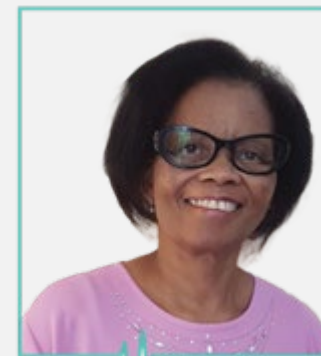
# ORGANISATIONAL STRUCTURE - Board

SAHPRA is accountable to the Minister of Health through a 15-member Board appointed by the Minister and in line with the prescripts of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended.

The Committees of the Board are made up in the main by the Board members



**Chairperson:**  
Prof Helen Rees

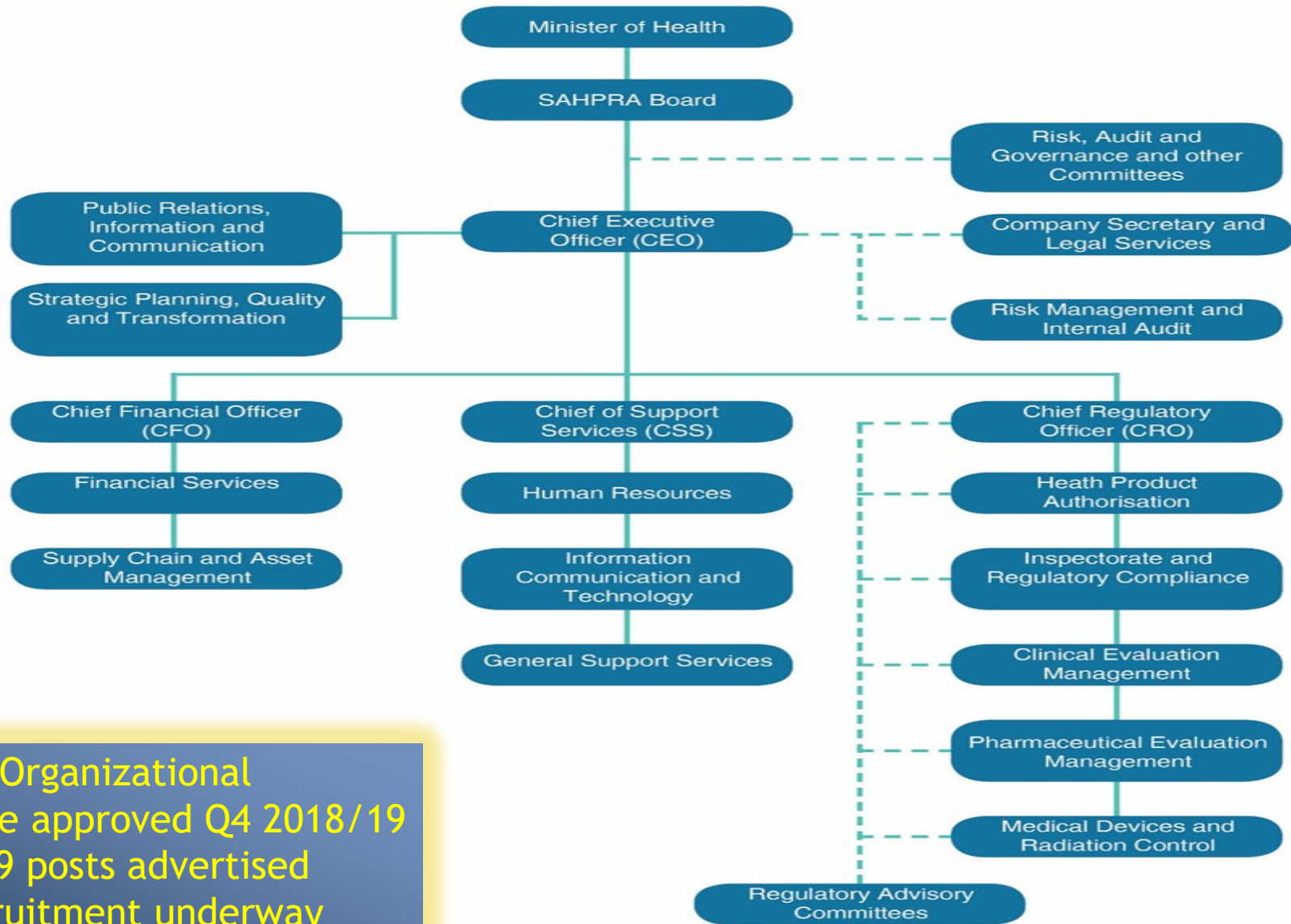


**Vice-Chairperson:**  
Ms Mandisa Hela

# ORGANISATIONAL STRUCTURE

## - Macro Organogram

Organizational Structure approved Q4 2018/19  
 109 posts advertised  
 Recruitment underway



# ORGANISATIONAL STRUCTURE

## - Executive leadership

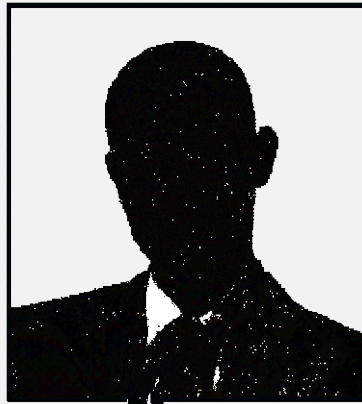


Chief Executive Officer (Acting) &  
Chief Regulatory Officer – 01 September 2019:

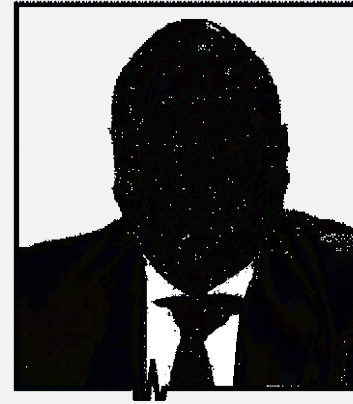
Ms Portia Nkambule



Dr B. Semete-Makokotlela Chief Executive  
Officer - Starting January 2020



Chief Financial Officer:  
Mr Molatlhegi Kgauwe



Company  
Secretary:  
Adv Teboho  
Nthotso

Chief Manager: Support Services: VACANT



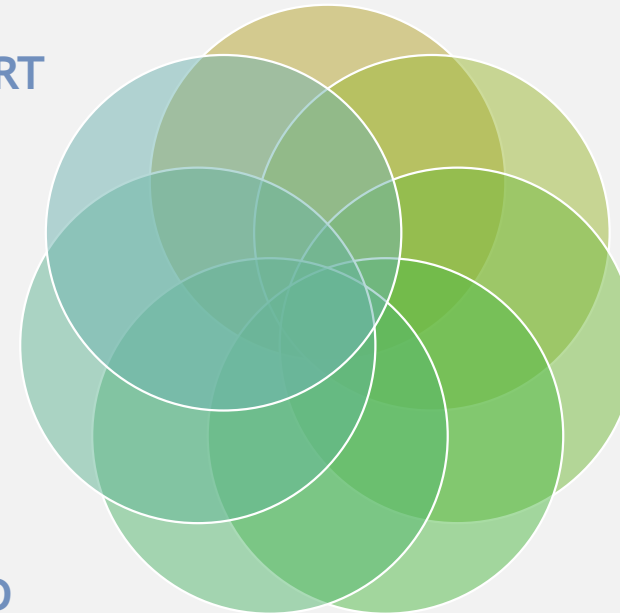
# ORGANISATIONAL ENVIRONMENT

**COMPLEX**

“START UP” ORGANISATION

INADEQUATE CORPORATE SERVICE SUPPORT

INADEQUATE TECHNICAL STAFF IN AN ESTABLISHED CORE PROGRAMME



INHERITED BACKLOG OF  $\approx 16\ 000$

EMERGENCY RELOCATION

PROLONGED LABOUR UNREST

RE-ENGINEERING OF OPERATIONS

# ACHIEVEMENTS

1

Relocation to CSIR in December 2018

2

Finalization of Organisational Structure in Quarter 4

3

Advertised 109 posts recruitment underway

4

Appointment of Key Executive Leadership Including CFO, Company Secretary and Director: ICT

5

Actively working to improve vigilance and reporting of adverse events, resulting in more active reporting from professionals and the public, and securing patient safety when engaging health products, both registered and unregistered.

6

Promulgation of a policy shift towards increased reliance models with other regulatory authorities that will be adopted in both the backlog and business-as-usual operational processes.

# ACHIEVEMENTS

7

The review of both operational and technological systems to ensure timeous delivery of this operational mandate within the ambits of internationally established best practice.

8

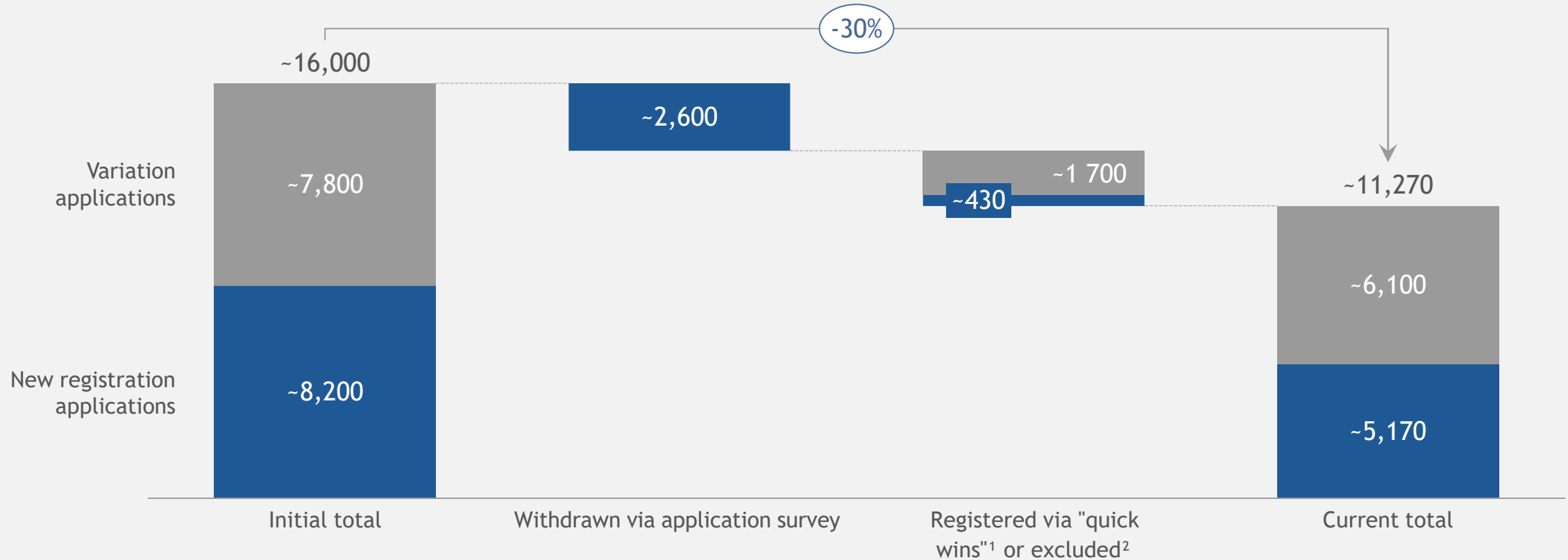
Development, approval and implementation of systems and frameworks to address new areas of health product regulation, including medical devices and radiation emitting devices and radioactive nuclides.

9

Development, approval and implementation of a re-engineered framework to eradicate the backlog of health product registrations and variations.

# Current number of backlog applications, to be cleared over the next 2 years

High-level



Note: Some data points are currently estimated due to data availability; 1. New registration applications registered via Project Starburst (~80) and variation certificates finalised (~1,700)  
 2. New registration applications excluded due to non-compliance (e.g. complementary medicines, no proof of submission)

# We are winning, but there is a way to go

- ✓ Backlog Clearance Program officially launched on 1 August 2019
- ✓ Procurement, customisation, and testing of new digital systems, including workflow tracking software
- ✓ Backlog Clearance Team recruited, with majority of on-boarding and training completed
- ✓ Regular, constructive engagement with industry and other health system stakeholders



# New processes pioneered in the Backlog Clearance Program will be used to reform "Business as Usual" (BAU)

## The Backlog Clearance Program

New policies and processes pioneered to effectively and efficiently clear the inherited medicines backlog



## Harmonised Backlog and BAU processes

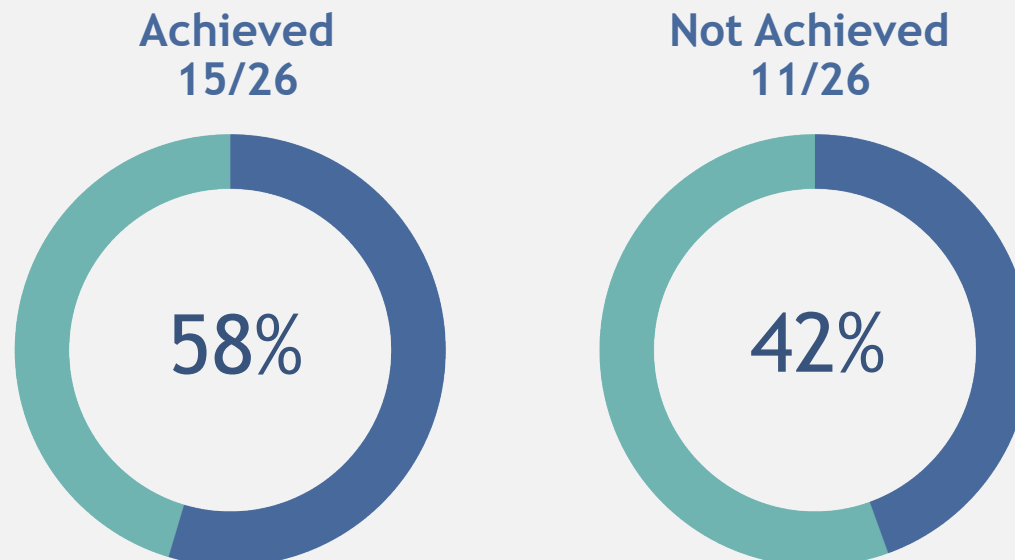
- ✓ New guidelines
- ✓ New processes
- ✓ New systems
- ✓ New efficiencies
- ✓ New ways of working together

## Business As Usual (BAU)

New medicines registration and variation applications received from 1 Feb 2018 onwards

Towards this end and through the work of SAHPRA, the following outputs were achieved in the performance year 2018/19:

A total of 26 Key Performance Indicators (KPIs) were relevant for the period under review



Within the core programme fulfilling the mandate of the organisation, the following performance outputs were noted for the entity:

- Issued a consolidated 5 910 licenses, permits and certificates from its Authorisation Management unit.
- 169 establishments were inspected for good manufacturing practice, good clinical practice, and good wholesale practice compliance.
- 64 permit holders, establishments and sites of narcotic and psychotropic substances were inspected.
- 147 human and animal clinical trials were reviewed within the predefined timeline.

# PERFORMANCE

- 682 clinical trials amendments were reviewed within the pre-defined timeline.
- 10 808 human, animal and complementary medicines - Section 21 applications - were reviewed within the pre-defined timelines in 2018/19.
- 20 new chemical entity and biological health products were registered.
- 181 generic and biosimilar health products were registered.
- Reports of new adverse events and signals that have been assessed, actioned and concluded were published every quarter and included eight media releases and 12 'Dear Healthcare Professional' letters.

# PERFORMANCE

- 349 medical device establishments were licensed.
- 2 960 new licenses were issued for radiation emitting devices and radioactive nuclides.
- Developed, approved and began implementation on the backlog framework to ensure the eradication of the backlog inherited from the previous MCC.
- Engaged with industry and other stakeholders 64 times to ensure bilateral and transparent communication.
- Strengthened 19 collaborative relationships with relevant stakeholders, and built support for the policy shift towards increased reliance models to be utilised within the entity's operations.



# PERFORMANCE

- Re-engineered Operational model will be supported by digitized systems to take the regulator into a more efficient business model.
- Extensive development on the website to become a more interactive portal of communication and information has begun.
- Data Integrity, Safety and Security have been included as critical components of the IT strategy.



# PERFORMANCE INDICATORS

## PROGRAMME 1

11 indicators  
6 met

55%

## PROGRAMME 2

2 indicators  
1 achieved

50%

## PROGRAMME 3

2 indicators  
0 achieved

0%

## PROGRAMME 4

8 indicators  
4 achieved

50%

## PROGRAMME 5

3 indicators  
3 achieved

100%

# Table 3: Programme 1: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
1	1	Establish, in a phased approach, a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA	% of funded positions filled	70%	91%	+21%	<p>Target exceeded</p> <p>During the year under review, the former MCC structure was utilised as the SAHPRA organogram was not yet finalised.</p> <p>The output therefore reflects staff as per this previous staff establishment.</p> <p>The new micro-organogram was approved in April 2019 and will be reported on during the 1st quarter of 2019/20.</p>

# Table 3: Programme 1: Annual Performance

KPI	Prog .	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
2	1	Establish, in a phased approach, a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA	% of staff trained as per annual performance plan	60%	0%	-60%	<p>Target not met</p> <p>Training planned through the National Department of Health Sector Education Training Unit (NDoH SETU) was not completed due to the labour unrest at the workplace and lack of staff in both SAHPRA and NDoH HR to facilitate and attend training.</p> <p>The critical HR Director position could not be filled, despite a recruitment initiative during the period under review. This position was subsequently re-advertised. Therefore, there was no training plan in place against which this KPI could be measured.</p> <p>However, staff have been undergoing informal training within various programmes.</p>

## Table 3: Programme 1: Annual Performance

KPI	Prog .	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
3	1	Maximise performance to improve organisational efficiency	% employee performance agreements signed no later than 31 May of each year	100%	24%	-76%	<p>Target not met.</p> <p>As at 31 May 2018, 51/211 performance agreements were signed.</p> <p>After 31 May 2018, 108/211 were signed.</p> <p>52/211 were unsigned and they are being addressed.</p> <p>Part of the difficulty in achieving this target was the labour unrest and relocation of SAHPRA that hampered this signing process.</p>

# Table 3: Programme 1: Annual Performance

KPI	Prog .	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
4	1	Develop a communication strategy to support improved external stakeholder interactions and relations	Communication strategy developed, approved and published	Approved communication strategy published on website	Communication strategy developed but not yet approved and published	-	<p>Target not met</p> <p>A draft Communications Strategy was finalised in the 1st quarter of 2019/20 and will be tabled for approval in the 2nd quarter of 2019/20.</p> <p>The delay is attributable to the anticipated support from the Government Communication and Information system (GCIS) not being secured to lend support to the development of the communication strategy.</p> <p>The Communications Committee was established in the 4th quarter to facilitate this KPI output.</p> <p>The appointment of the Director: Communications has been made. The post will be occupied on 1 June 2019 of 2019/20.</p> <p>ICT infrastructure and web development to support this KPI is also in process.</p>

# Table 3: Programme 1: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
5	1	Create public and stakeholder awareness about the mandate of SAHPRA	Number of media and communication events and stakeholder meetings	4	64	+60	<p>Target exceeded</p> <p>There was a significant increase in initiatives aimed at ensuring that stakeholder communication was effective, particularly during labour unrest and building shutdown.</p> <p>Moreover, communications that had a significant public health impact (such as safety advisories) were prioritised.</p> <p>There were also increased stakeholder engagements with regards to the development of the backlog framework.</p> <p>This KPI will be revised to better delineate engagements per stakeholder constituency.</p>

## Table 3: Programme 1: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
6	1	Implement good governance, oversight and accountability through appropriate delegation, including Financial Management and compliance with PFMA requirements	Audit Outcome	Unqualified Audit Report	Qualified Audit Report		<p>Target not met.</p> <p>This is mainly due to lack of and limited internal controls as a result of capacity constraints</p>

# Table 3: Programme 1: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
7	1	Ensure that the monitoring and inspection of information stored on SAHPRA Information and Communication Technology (ICT) facilities and services are performed in an appropriate and responsible manner	ICT policy developed and approved	Approved ICT policy	ICT policy developed and approved	-	Target met
8	1	Ensure a comprehensive plan is in place that outlines how technology should be used to meet IT and SAHPRA goals	ICT strategy developed and approved	Approved ICT strategy	ICT strategy developed and approved	-	Target met

# Table 3: Programme 1: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
9	1	Share, co-operate and strengthen collaborative initiatives with relevant stakeholders to support the mandate of SAHPRA	Number of collaborative relationships strengthened	2 MoUs	19	+17	Target exceeded  The significantly increased number of MoUs is due to a policy shift towards increased reliance models with other regulatory authorities that will be adopted in both the backlog and business-as-usual operational processes.
10	1	Enter into agreements with contract laboratories to support quality assurance and control function of Regulator	Number of service level agreements in place with contract laboratories	1	1	-	Target met  Contract signed with National Control Laboratory for Biological Products.

# Table 3: Programme 1: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
11	1	Maintain medicine and medical device registers	Updated medicine and medical device registers published on website quarterly	Quarterly update report published	Quarterly update reports published for 2 quarters	-2 quarters	<p>Target not met.</p> <p>SAHPRA is currently using the old MCC notification of registration system to publish quarterly reports.</p> <p>SAHPRA is in the process of developing an electronic register for publication on the website.</p> <p>3rd and 4th quarter updates were unpublished owing to issues with labour unrest, which affected staff capacity, and relocation, which affected access to the ICT infrastructure.</p>

# Table 4: Programme 2: Annual Performance

KPI	Prog .	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
12	2	Take regulatory decisions on all backing applications	Backlog framework developed	Backlog framework developed and implemented	Backlog framework developed, piloted and implementation commenced		Target met
			% of backlog applications with regulatory decisions taken	Not applicable for 2018/19	Not applicable for 2018/19		Not applicable for 2018/19

# Table 4: Programme 2: Annual Performance

KPI	Prog	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
13	2	Issue of licence, permits, registration certificates, certificates of establishments and health products for applications received for medicines and medical devices within a specified timeline after regulatory decision taken	% of licences, permits and certificates issued within predefined timeline on quarterly basis	70%	47 %	-2 quarters	<p>Target not met</p> <p>The non-compliance can be attributed to the labour unrest and relocation in the 2nd and 3rd quarters. This resulted in a lack of staff to support targeted output.</p> <p>Strategies to address this backlog are now being implemented successfully.</p> <p>5 910/12 648 certificates, permits and licences were issued in 2018/19</p>

# Table 5: Programme 3: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
14	3	Inspect establishments to ensure compliance with relevant GxP and established standards within predefined timelines	% of establishments due for inspection inspected annually	45%	37%	8%	<p>Target not met</p> <p>The annual target overall was underachieved by 8% due to a drop in performance in the 2nd and 3rd quarters.</p> <p>During these quarters, the workforce was limited because of labour unrest and building shutdown affecting inspectorate functioning.</p> <p>The relocation of SAHPRA in the 3rd and 4th quarters further affected delivery. This trend has now been reversed with the backlog of inspections being addressed in Q1 2019/20.</p> <p>169/463 establishment inspections were conducted in 2018/19.</p>

# Table 5: Programme 3: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
15	3	Inspect permit holders/ establishments of narcotic and psychotropic substances to ensure compliance with established standards within predefined timelines	% of permit holders, establishments and sites of narcotic and psychotropic substances inspected annually	20%	34%	14%	<p>Target exceeded</p> <p>The focus in the 3rd and 4<sup>th</sup> quarters was on cannabis sites and applications. Inspectors were mobilised out of the office during labour unrest and relocation. Routine work was deferred with minimal risk as these sites were GMP-compliant.</p> <p>This KPI target will be revised to better align to international best practice norms.</p> <p>64/190 narcotic and psychotropic inspections were completed in 2018/19.</p>

# Table 6: Programme 4: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
16	4	Evaluate clinical trial protocols received in accordance with defined standards	% of clinical trial applications evaluated within an evaluation cycle	85%	95%	95%	<p>Target exceeded</p> <p>Work output was supported by community service pharmacists deployed to the unit.</p> <p>147/154 clinical trials were reviewed within the predefined timeline in 2018/19.</p>
17	4	Evaluate clinical trial protocol amendments in accordance with defined standards	% of permit holders, establishments and sites of narcotic and psychotropic substances inspected annually	72%	73%	1%	<p>Target exceeded</p> <p>Work output was supported by community service pharmacists deployed to the unit.</p> <p>682/929 clinical trial amendments were reviewed within the predefined timeline in 2018/19.</p>

# Table 6: Programme 4: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
18	4	Evaluate the applications received for sale of unregistered health products in accordance with defined standards	% of applications for the sale of an unregistered health product evaluated within a specified timeline	75%	80%	5%	<p>Target exceeded</p> <p>Digitisation and deployment of community service pharmacists allowed for faster processing over the last two quarters.</p> <p>10 808/13 433 applications for the sale of an unregistered health product evaluated within a specified timeline.</p>
19	4	Scientific evaluation of all NCE/biological applications submitted for regulatory decision	40%	0%	0%	-40%	<p>Target not met</p> <p>Labour unrest, relocation and ICT difficulties hampered improved output. The 275-day timeline was not yet achievable. The impact of the backlog and re-engineering will only be evident in 2020/21.</p> <p>20 NCEs and biologicals were registered in the year 2018/19.</p> <p>The range of time taken to register an NCE/biological was 395-3188 working days.</p>

## Table 6: Programme 4: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
20	4	Scientific evaluation of new health product amendments submitted for regulatory decision	% of NCE/Biological amendments evaluations concluded with a regulatory decision within 120 working days. (time spent at regulator)	40%	0	-40%	Target not met  Labour unrest, relocation and ICT difficulties hampered improved output. The 120-day timeline was not yet achievable. The impact of the backlog and re-engineering will only be evident in 2020/21.

# Table 6: Programme 4: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
21	4	Scientific evaluation of generic/biosimilar applications submitted for regulatory decision	% of generic/biosimilar application evaluations concluded with a regulatory decision within 180 working days (time spent at regulator)	40%	3%	3%	<p>Target not met</p> <p>Labour unrest, relocation and ICT difficulties hampered improved output.</p> <p>The 180-day timeline was not yet achievable. The impact of the backlog and re-engineering will only be evident in 2020/21.</p> <p>181 generics and biosimilars were registered in the year 2018/19.</p> <p>The range of time taken to register a generic/biosimilar was 167-3 354 working days.</p> <p>Five products in the 3rd quarter were registered over a period of 167 working days.</p>

# Table 6: Programme 4: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
22	4	Scientific evaluation of generic/biosimilar amendments submitted for regulatory decision	% of generic/biosimilar amendment evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)	40%	0%	-40%	<p>Target not met</p> <p>The 120-days timeline was not yet achievable. The impact of backlog and re-engineering will only be evident in 2020/21. Labour unrest, relocation and ICT difficulties hampered improved output.</p>

# Table 6: Programme 4: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
23	4	Investigate, monitor, analyse solicit and act upon existing and new adverse events, interactions and signals emerging from post-marketing surveillance and vigilance	Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded	Bi-annual reports to the public	Quarterly reports to the Public for three quarters	+1	<p>Target exceeded</p> <p>SAHPRA is actively working to improve vigilance and reporting of adverse events, resulting in more active reporting from professionals and the public. SAHPRA is moving towards consolidated vigilance quarterly reports in the 2019/20 performance year.</p> <p>This KPI will be revised to better delineate quarterly reporting of adverse events and signals.</p>
				Not applicable for 2018/19	Not applicable for 2018/19		
			An inclusive vigilance framework for all health products developed and approved				

# Table 7: Programme 5: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
24	5	License medical device establishments that are compliant with prescribed reference standards	% of medical device establishment licence applications finalised within predefined timelines	35%	70%	35%	<p>Target exceeded</p> <p>Work output was supported by community service pharmacists deployed to the unit to address the backlog accumulated from 2017/18 due to a large number of applications received in that period.</p> <p>349/500 medical device establishments were licensed in 2018/19.</p>
25	5	License medical device establishments that are compliant with prescribed reference standards	A system to register medical devices has been developed and implemented	72%	73%		<p>Target met</p> <p>A system for certain medical devices is in place for group 3 and 4 devices.</p> <p>Further, a system exists in the radiation control unit.</p> <p>The system will be re-engineered to improve the scope and capability of medical device registrations in 2019/20.</p>

# Table 7: Programme 5: Annual Performance

KP I	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	Annual Achievement 2018/19	Variance	Reasons for Variance
26	5	Evaluate radiation emitting devices and radioactive nuclides for regulatory decision	Evaluate radiation emitting devices and radioactive nuclides for regulatory decision	35%	An approved system to register medical devices have been implemented	+64%	<p>Target exceeded</p> <p>Targets in radiation control are passively determined by applications received from applicants. Currently, three of the four units within this area of work process 100% of the licences. The 4th unit (ionising radiation devices) has a three-month backlog. Review and re-engineering of operations are being undertaken in radiation control to bring alignment to the mandate of the Act and will be implemented in the 2019/20 performance year. This KPI will be revised to better delineate this change.</p> <p>2 960/2 978 new licences were issued for radiation emitting devices and radioactive nuclides.</p>

# Audit Outcome

## Financial

### **QUALIFIED**

Basis of the  
qualification :

Revenue  
Deferred Income  
Operating Expenses

## Performance

Programme 2: Health Product  
Authorisation

**QUALIFIED**

Programme 3: Inspectorate  
and Regulatory Compliance

**DISCLAIMER**

Programme 4: Medicines  
Evaluation and Registration

**QUALIFIED**

# FINANCE BUDGET VS ACTUAL

	Approved Budget	Actual	Variance	Reason
Fee income	90,681,000	72,059,772	-18,621,228	Fee income is below budget due to services that could not be rendered as a result of industrial action at the NDOH premises.
Interest received	0	4,907,134	4,907,134	Interest is higher than budget due to unspent funds
Government grants	125,189,000	125,189,000	0	
Goods and services in kind from NDoH	0	29,124,227	29,124,227	NDOH paid for SAHPRA expenses for the period between 1 February 2018 to 31 March 2018. The expenditure is accounted for as an in-kind donation by the NDOH
<b>Total revenue</b>	<b>215,870,000</b>	<b>231,280,133</b>	<b>15,410,133</b>	

# FINANCE BUDGET VS ACTUAL

	Approved Budget	Actual	Variance	Reason
Expenditure of employees	149,145,380	119,066,656	30,078,724	Employee related costs are lower than budget due to vacancies.
Goods and Service	66,724,620	51,917,018	14,807,602	Operating expenses is less than budget due to less transactions as a result of the industrial action
Goods and services in-kind from the National Department of Health	0	29,124,227	- 29,124,227	NDOH paid for SAHPRA expenses for the period between 1 February 2018 to 31 March 2018. The expenditure is accounted for as an in-kind donation by the NDOH
Total Expenditure	215,870,000	200,107,901	15,762,099	
Surplus	0	31,172,232		

South African Health Products Regulatory Authority incurred the following irregular expenditure as at year end 31 March 2019:

Irregular Expenditure - current year: R1,206,785

**Reason for irregular expenditure**

The irregular expenditure relates to non-compliance with Supply Chain Management regulations. This emanated from the lack of capacity within the SCM unit and personnel with the required skills.

**Planned response to irregular expenditure**

Capacitate the SCM unit and train staff on SCM processes.

# AUDIT ACTION PLAN

Capacitating the whole organization

Re-engineering of business processes

Update standard operating procedures

Upskilling of staff

Quality Management System

Improve internal controls

Revise key performance indicators

# FINANCIAL SUSTAINABILITY

SAHPRA has requested additional funding allocation which was declined.

SAHPRA has applied for retention of surplus funds amounting to R 18m. Awaiting outcome.

SAHPRA is in the process of revising fees.



**Thank you!**

**Q & A**