SAHPRA
South African
Health Products
Regulatory Authority

Presentation to the Portfolio Committee on Health on the SAHPRA 2021/22 Annual Report

13 October 2022

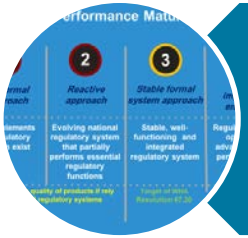
Presentation Outline

- Vision, Mission & Values
- Introduction
- Service Delivery Environment
- Organisational Environment
- Institutional Response to COVID-19
- Global Partnerships
- Overall Performance
- Performance per Programme:
  - Programme 1: Leadership and Support
  - Programme 2: Health Products Authorisation
  - Programme 3: Inspectorate and Regulatory Compliance
  - Programme 4: Clinical and Pharmaceutical Evaluation
  - Programme 5: Medical Devices and Radiation Control
- Human Resource Information
- Financial Information
- Conclusion

SAHPRA
South African Health Products Regulatory Authority

2022 highlights for SAHPRA

Unqualified audit opinion of the 2021/22 FY



Achieved ML3 for vaccines regulatory oversight including ML 4 for lot release. The first NRA in the continent to achieve this

99.5% of the backlog cleared as at September 2022. project will be completed by November 2022

SAHPRA
South African Health Products Regulatory Authority

Vision, Mission & Values

Vision

An **agile** and **responsive African** health products regulator that is **globally recognised** as an enabler of access to safe, effective and quality health products in South Africa

Mission

To **promote access to health products** and **protect human and animal health** in South Africa through making science-based regulatory decisions

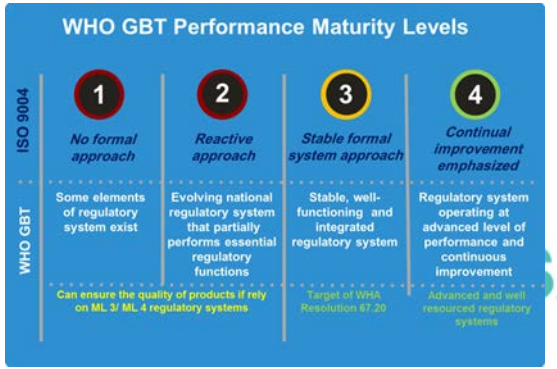
Values

- Ubuntu
- Responsiveness
- Integrity
- Transparency
- Efficiency
- Excellence

SAHPRA
South African Health Products Regulatory Authority

Introduction

- 4th year SAHPRA audited as a Schedule 3A public entity.
- As the regulator of national health products, SAHPRA was at the core of the South African national response strategy for a pandemic
  - Led the pack by playing a decisive role in making evidence-based decisions
  - Monitoring on the adverse events of COVID-19 related health products, including COVID-19 Vaccines
- Systems developed for the COVID-19 emergency are now being adapted for other products required for new and ongoing priority public health needs to enable effective vigilance.
- Recent declaration by World Health Organization (WHO) of SAHPRA's maturity level 3
  - Confirms stability & well-functioning Regulator
  - Boost public's confidence & international recognition.



SAHPRA
South African Health Products Regulatory Authority

Service Delivery Environment

Health Products Registration

- Implemented **Policy on Priority Review Pathways** for medicines encompassing vaccines, human immunodeficiency virus, oncology and tuberculosis.
- To reduce registration timelines, piloted pre-submission meetings as a 1st step in the application process.
- **Backlog reduction strategies** in generic medicine registrations included using assessment reports from Recognised Regulatory Authorities and SAHPRA.
- Due to limited **funding from National treasury for capacitation** of the organization, the SAHPRA leadership focused efforts to raise funding

Post Marketing Surveillance

- The **lot release function for vaccines** received the highest ranking by WHO of **Maturity level 4,** indicating that robust processes are in place to ensure quality vaccines are available in the country.
- Increased usage of the MedSafety App.
- Transparency promoted through **weekly publication of vaccine safety statistics** in collaboration with the Council for Scientific and Industrial Research.
- Conducted inspections at facilities that were reported to be operating non-complaint to the Medicines Act

Executing our Mandate

- Mandate challenged through public protests and political pressure in areas such as cannabis, COVID-19 vaccines and therapeutics
- Several litigation cases brought against SAHPRA
  - Relied on science and evidenced-based decisions
  - Minimal disruptions to business operations although security measures enhanced due to safety concerns for staff
  - Continued support from the state required to ensure autonomy protected.

SAHPRA
South African Health Products Regulatory Authority

Organisational Environment (1)

- In September 2021, new SAHPRA Board was appointed
  - Composed of members who had served on the inaugural SAHPRA Board complemented by new members.

SAHPRA Board Members

SAHPRA
South African Health Products Regulatory Authority

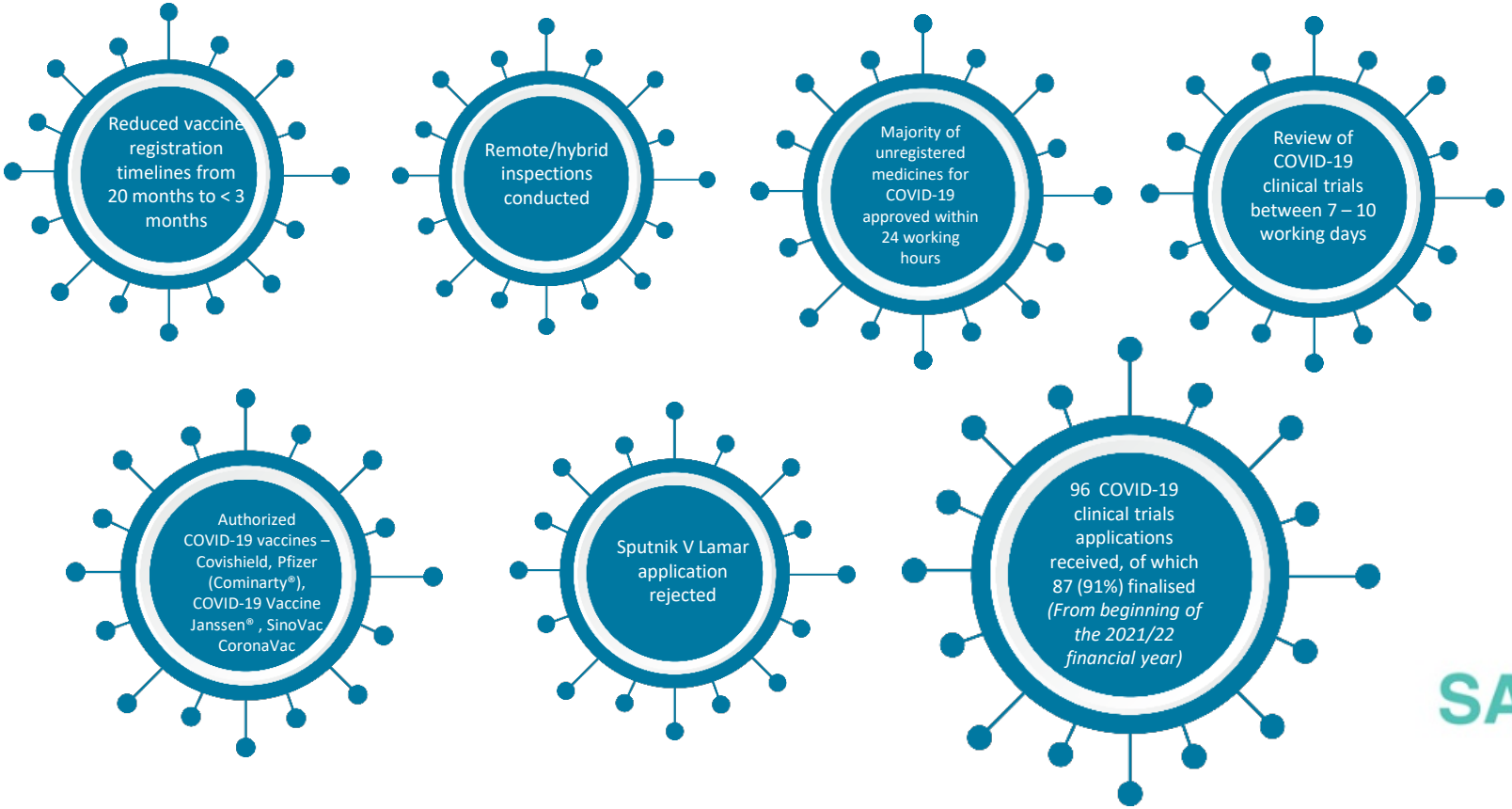
Organisational Environment (2)

- Focused on cultivating and sustaining a high-performance culture.
- Recruited externally whilst giving opportunity to internal employees.
  - Important that key talent is retained.
- All staff members moved from the National Department of Health through the Labour Relations Act Section 197 were transferred to SAHPRA.

Management team during Tactical Planning Session

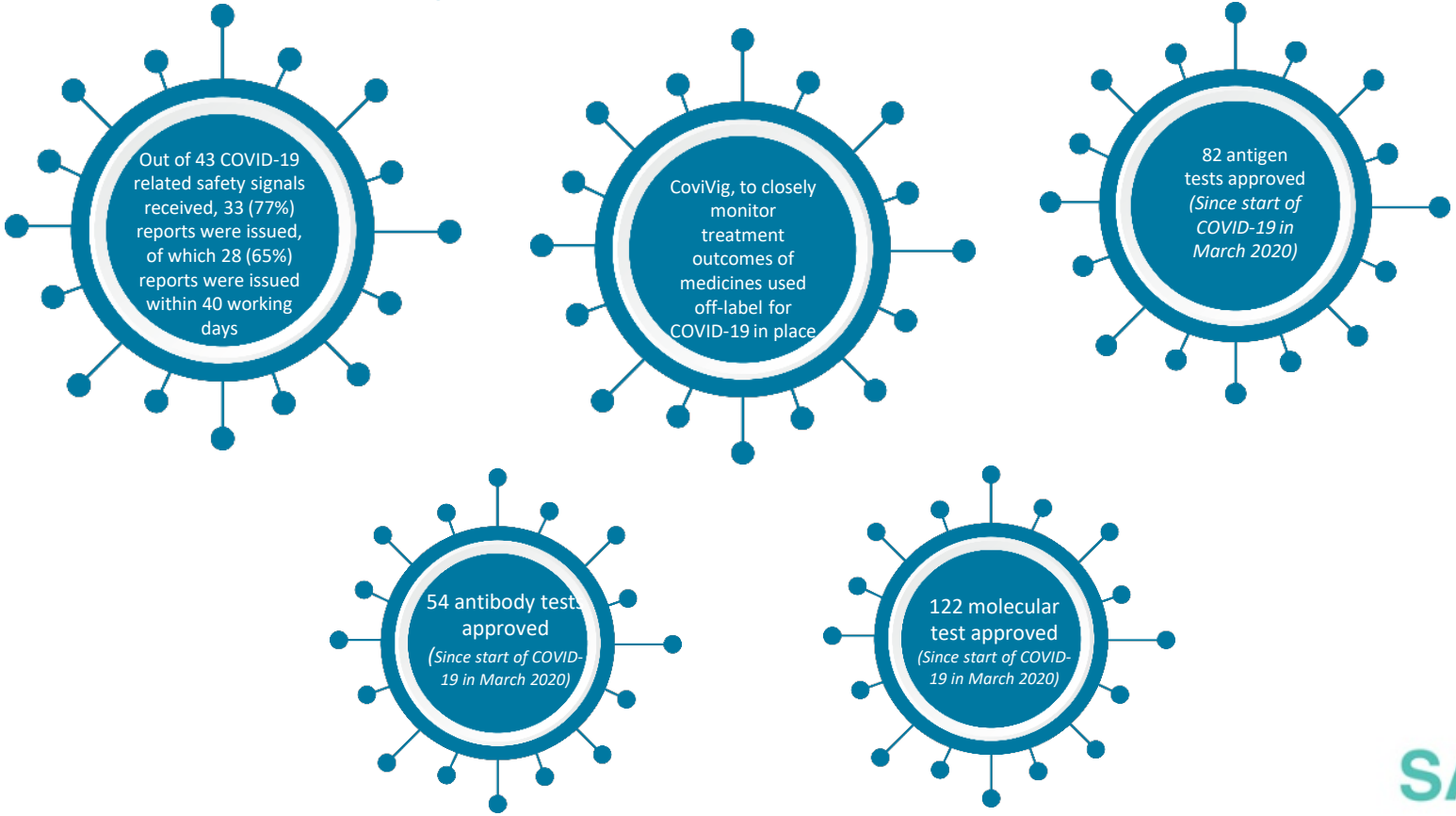
SAHPRA
South African Health Products Regulatory Authority

Institutional Response to COVID-19 (1)



SAHPRA
South African Health Products Regulatory Authority

Institutional Response to COVID-19 (2)



SAHPRA
South African Health Products Regulatory Authority

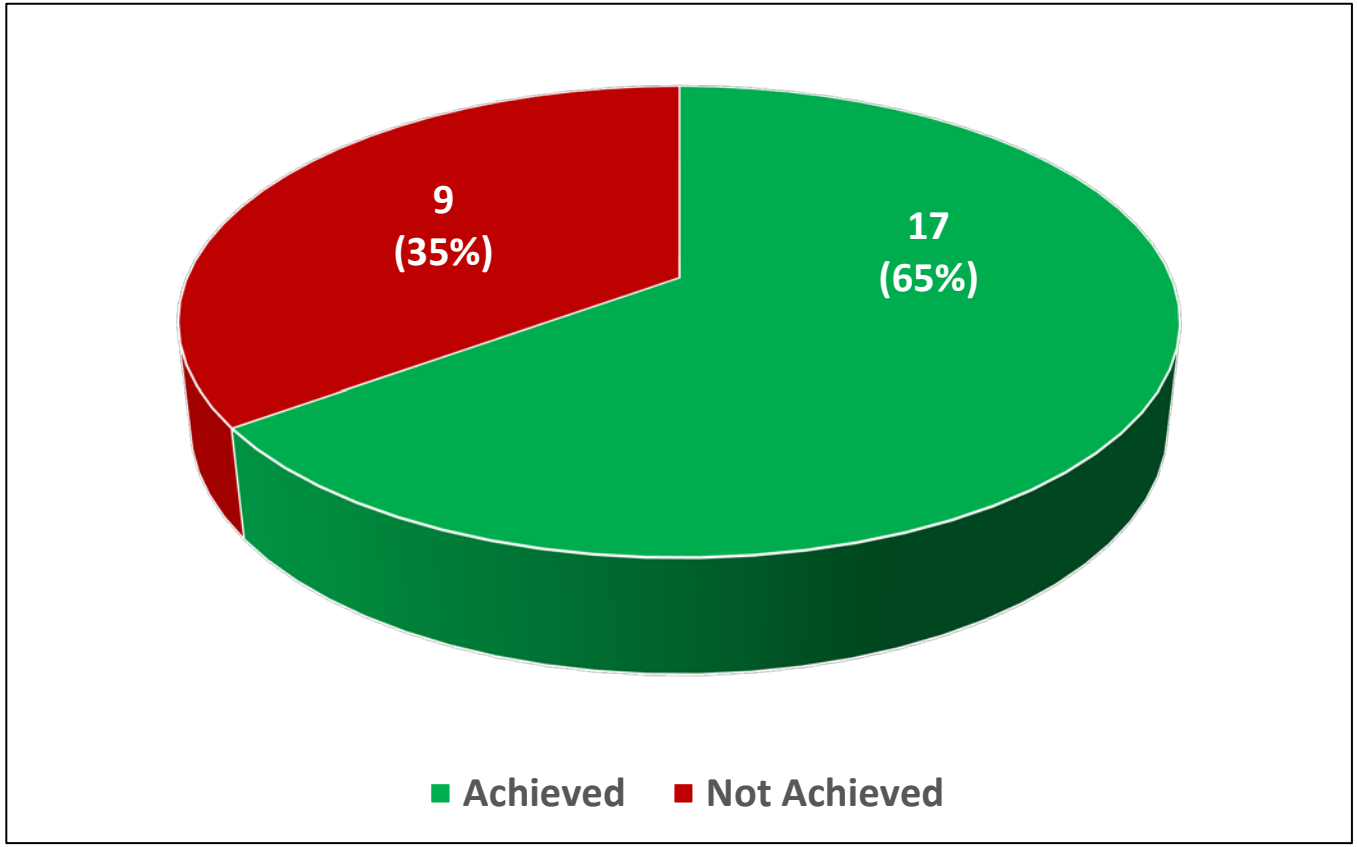
Global Partnerships

- Participated in WHO workshops
- SAHPRA is a Member of the International Coalition of Medicines Regulatory Authorities.
- SAHPRA is a member of Steering Committee of the African Vaccine Regulatory Forum
- Conducted joint inspections with WHO.

Staff engagement with WHO Chief Scientist, Dr Soumya Swaminathan during a site visit

SAHPRA
South African Health Products Regulatory Authority

Overall Performance



SAHPRA
South African
Health Products
Regulatory Authority

P1: Leadership & Support (1)

Finance

Revenue of R169 million was generated from fees

- Increased interest and application revenue.

Information Technology

Acquisition and implementation of systems to drive the digital transformation remained a priority.

- A number of existing systems, such as the Digital Variations Portal and the Section 21 Portal enhanced to improve functionality.
- Security Penetration Testing Simulation completed.

SAHPRA
South African Health Products Regulatory Authority

P1: Leadership & Support (2)

Communi-cations

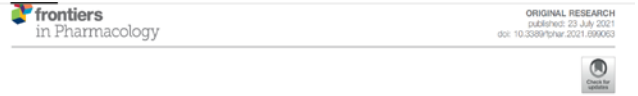
- Complaints mechanism implemented on SAHPRA website that allows stakeholders to lodge complaints on SAHPRA services.
- Stakeholder outreach programme focused on public outreach
  - Engaging mainstream and community media in both English and various other indigenous languages.
  - 91 TV and radio interviews.
  - Two videos focusing on Adverse Effects Following Immunisation translated into five other official languages.

Interview on illicit medicines sold at Nyanga, Cape Town

SAHPRA
South African
Health Products
Regulatory Authority

P1: Leadership & Support (3)

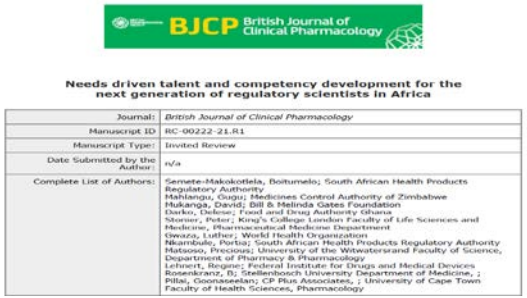
- Contributed articles that focused on various topical issues.
  - Articles published in international journals such as Frontiers in Medicine Regulatory Science, British Journal of Clinical Pharmacology and the Vaccine Research Journal.


frontiers in Pharmacology

ORIGINAL RESEARCH
published: 23 July 2021
doi: 10.3389/fphar.2021.690063

South African Regulatory Authority: The Impact of Reliance on the Review Process Leading to Improved Patient Access

Andrea Keyter[1], Sam Salek[1,2], Lorraine Danks[3], Portia Nkambule[3], Boitumelo Semete-Makokotlela[3] and Stuart Walker[1,4,5]*


BJCP British Journal of Clinical Pharmacology

Needs driven talent and competency development for the next generation of regulatory scientists in Africa

Journal:	*British Journal of Clinical Pharmacology*
Manuscript ID	RC-00222-21.R1
Manuscript Type:	Invited Review
Date Submitted by the Author:	n/a
Complete List of Authors:	Semete-Makokotlela, Boitumelo; South African Health Products Regulatory Authority Mahlangu, Gugu; Medicines Control Authority of Zimbabwe Mukanga, David; Bill & Melinda Gates Foundation Darko, Delese; Food and Drug Authority Ghana Stoner, Peter; King's College London Faculty of Life Sciences and Medicine, Pharmaceutical Medicine Department Gwaza, Luther; World Health Organization Nkambule, Portia; South African Health Products Regulatory Authority Matsoso, Precious; University of the Witwatersrand Faculty of Science, Department of Pharmacy & Pharmacology Lehnert, Regine; Federal Institute for Drugs and Medical Devices Rosenkranz, B; Stellenbosch University Department of Medicine, ; Pillai, Goonaseelan; CP Plus Associates, ; University of Cape Town Faculty of Health Sciences, Pharmacology

- Provided live streaming services during an event held running parallel with the World Conference on Pharmacometrics in Cape Town.

CEO presenting at the official opening at WCoP 2022

SAHPRA South African Health Products Regulatory Authority

P1: Leadership & Support (4)

Human Resources

- Human Resource Indabas held to promote employee engagements.
- Operated with a complete leadership team
  - Includes all the executives and senior managers.
- Recruitment to fill the prioritized vacant positions were accelerated to ensure business continuity.
- Launched the ICAS Employee Assistance Programmed.

Training on dossier assessment for clinical assessors within African regulatory agencies

SAHPRA South African Health Products Regulatory Authority

P1: Leadership & Support (5)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
1. Unqualified audit opinion obtained	Qualified audit opinion was obtained for the 2020/21 financial year	Target was not achieved	Supporting evidence for comparative figures relating to income received in advance and fee income could not be obtained for audit purposes
2. Revenue of R162 million generated from fees	Revenue of R169 million was generated from fees	Target was exceeded by R7 million	Increase in applications received
3. Zero	R28 million *The breakeven point was exceeded by R28 million, which is an accounting surplus reported*	Target was exceeded by R28 million	Under expenditure on Compensation of Employees and operational expenditure
4. 40% prioritised recommendations from the survey implemented	Out of 3 prioritised recommendations from the survey, the following 2 (67%) were implemented: • A web query system. Out of the 1 103 queries received, 623 (56%) were responded to • Out of a staff establishment of 395, 266 (67%) posts were occupied which included positions that were filled by employees who were placed on higher grades during the administrative placement exercise	Target was exceeded by 27%	Filling of vacant posts was prioritised

SAHPRA
South African Health Products Regulatory Authority

P1: Leadership & Support (6)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
5. **50% of the change management intervention implemented**	Out of 13 change management interventions identified, 12 (92%) were implemented	Target was exceeded by 42%	Number of staff engagements were increased to address topical organisational matters
6. **30% of the Workplace Skills Plan implemented**	Out of 23 planned training interventions in the Workplace Skills Plan, 9 (39%) were implemented	Target was exceeded by 9%	Implementation of training initiatives were accelerated
7. **60% budgeted positions filled**	Out of 55 budgeted positions, 53 (96%) were filled	Target was exceeded by 36%	Recruitment was prioritised to resource under capacitated units
8. **3 business processes digitalized**	Section 21 business process was digitised in June 2021 Development of an online application submission system was in progress Leave application process was digitalised	Target was missed by 2	Digitisation had to be outsourced due to resignation of the only Software Developer, resulting in delays due to the lack of financial resources

SAHPRA
South African Health Products Regulatory Authority

P2: Health Products Authorisation (1)

- In 2018, SAHPRA inherited a backlog of over 16 000 medicine applications.
  - To address backlog, SAHPRA established a Backlog Clearance Programme.
  - To increase the finalisation of new registration applications, initiated a risk-based assessment pilot study.
  - Risk-based assessment study has shown that the quality aspects of approximately 85% of applications were evaluated and finalised within 3 months.
  - To reach the project finalisation date of 31 December 2022, the 2nd phase of this pilot study rolled-out during the 2022/23 financial year.
  - **The current completion rate of the backlog is at 99,5%**

- Key focus was to work towards obtaining a Maturity Level 3 based on the WHO Global Benchmarking Tool.
  - Final benchmarking assessment was concluded during the 2022/23 financial year.

SAHPRA
South African Health Products Regulatory Authority

P2: Health Products Authorisation (2)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
9. 95% medicine registrations backlog cleared	Out of 3 395 backlog applications for medicine registrations received, 2 557 (75%) were cleared	Target was missed by 20%	Limited human resource capacity in the Clinical Pre-Registration Unit, slow finalisation of the Quality-Bio-Equivalence aspects of applications as well as extensions requested by applicants due to COVID-19 pandemic
10. 95% medicine variation applications backlog cleared	Out of 3 611 backlog applications for medicine variations received, 3 428 (95%) were cleared	Not applicable	Not applicable
11. 80% New Chemical Entities finalised within 590 working days	Out of 246 New Chemical Entities applications received, 44 (18%) were finalised Out of the 44 finalised, all 44 (100%) were finalised within 590 working days	Target was exceeded by 20%	Applications that are novel treatments, for unmet medical needs were prioritised
12. 60% generic medicines finalised within 250 working days	Out of 2 075 generic medicine applications received, 184 (9%) were finalised Out of the 184 finalised, 148 (80%) were finalised within 250 working days	Target was exceeded by 20%	Applications that are novel treatments, for unmet medical needs were prioritised

SAHPRA
South African Health Products Regulatory Authority

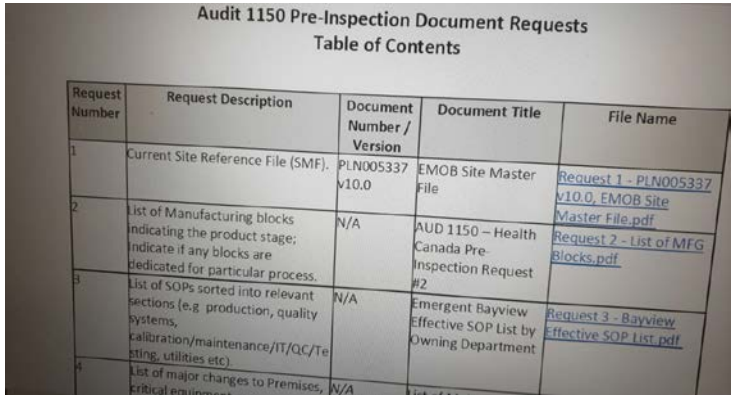
P2: Health Products Authorisation (3)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
13. **40% Quality Management System requirements implemented**	73% of Quality Management System requirements were implemented	Target was exceeded by 33%	Some of the planned activities were completed earlier than planned in preparation for the Global Benchmarking Tool by the WHO
14. **WHO maturity level 3 obtained**	Based on the WHO provisional assessment report received in November 2021, an Institutional Development Plan was developed to address the recommendations	Target was not achieved	The roadmap was adjusted by WHO for the assessment to be concluded during October 2022. The COVID-19 pandemic travel restrictions resulted in the late start of the assessment

SAHPRA
South African Health Products Regulatory Authority

P3: Inspectorate & Regulatory Compliance (1)

- Remote inspections conducted
  - For new applications, routine inspections and unannounced inspections.
  - As part of a joint inspection with Health Canada and European Medicines Agency, virtual inspection conducted at the emergent site that produces the drug substance for J&J COVID-19 Vaccine.
- Participated in WHO Pre-Qualification inspection in India.



Audit 1150 Pre-Inspection Document Requests
Table of Contents

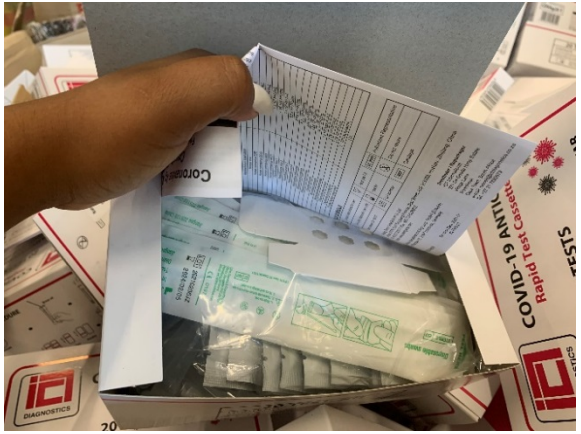
Request Number	Request Description	Document Number / Version	Document Title	File Name
1	Current Site Reference File (SMF).	PLN005337 v10.0	EMOB Site Master File	Request 1 - PLN005337 v10.0, EMOB Site Master File.pdf
2	List of Manufacturing blocks indicating the product stage; indicate if any blocks are dedicated for particular process.	N/A	AUD 1150 – Health Canada Pre-Inspection Request #2	Request 2 - List of MFG Blocks.pdf
3	List of SOPs sorted into relevant sections (e.g. production, quality systems, calibration/maintenance/IT/QC/Testing, utilities etc)	N/A	Emergent Bayview Effective SOP List by Owning Department	Request 3 - Bayview Effective SOP List.pdf
4	List of major changes to Premises,	N/A		

Virtual inspection

- Through co-operation with law enforcement agencies such as the South African Police Service, arrests were made and prosecution of individuals who contravened the Medicines and Related Substances Act
  - Contraventions ranged from illegal importation to illegal manufacturing.
  - Increased actions against registered and unregistered personnel contravening the Pharmacy Act.

SAHPRA
South African Health Products Regulatory Authority

P3: Inspectorate & Regulatory Compliance (2)



Unapproved repackaging (manufacture) of COVID-19 Test kits

3-ply mask with SAHPRA logo destruction

SAHPRA
South African Health Products Regulatory Authority

P3: Inspectorate & Regulatory Compliance (3)

- Upon invitation by the International Narcotics Control Board, SAHPRA co-sponsored and participated in 2 parallel events at the 65th Session of the Commission on Narcotic Drugs, focusing on cannabis related matters.
- Progress on medical cannabis
  - Licenses issued to establishments/entities that meet the regulatory requirements for cultivation, manufacture or distribution of cannabis for medicinal purposes.
  - Licence holders successfully export to countries such as Canada, United States of America, Portugal, Israel, Switzerland, Macedonia, Lesotho, Zimbabwe, Germany and the United Kingdom.

Province	Number of Application	Resolution letters issued	Licenses Issued
Gauteng	86	17	14
Limpopo	21	06	04
KwaZulu Natal	57	07	07
Eastern Cape	21	05	05
Western Cape	61	17	15
Mpumalanga	13	01	01
North West	16	06	05
Northern Cape	07	03	01
Free State	25	02	04
Total	**307**	**67**	**56**

SAHPRA
South African Health Products Regulatory Authority

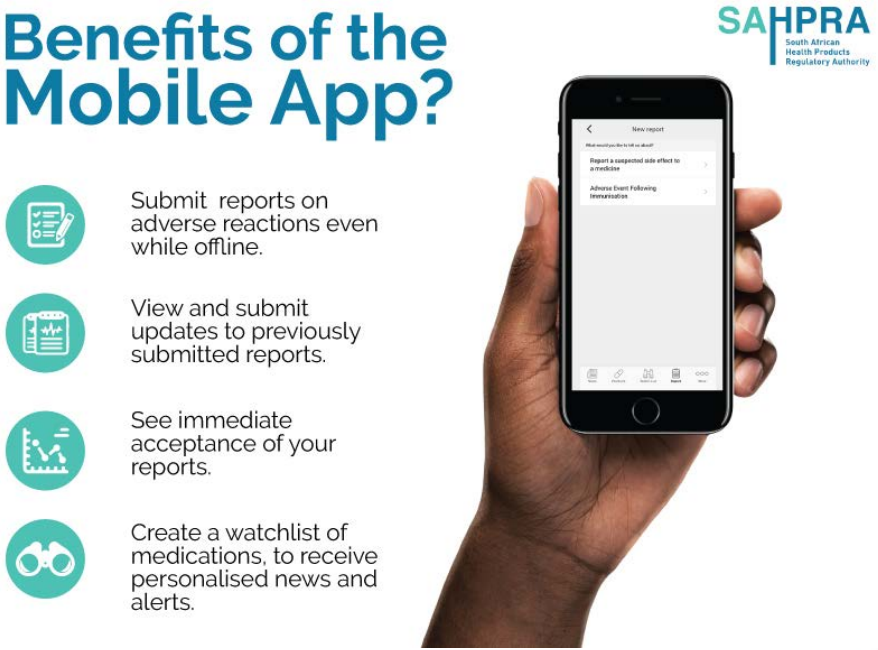
P3: Inspectorate & Regulatory Compliance (4)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
15. 60% new GMP and GWP related licenses finalised within 125 working days	Out of 64 new GMP and GWP related licences applications received, 31 (48%) were finalised Out of the 31 finalised, 13 (42%), were finalised within 125 working days	Target was missed by 18%	8 out of the 31 (26%) licenses finalised were affected by the COVID-19 lockdown restrictions as inspections could not be conducted
16. 70% permits finalised within 20 working days	Out of 4 553 permit applications received, 4 474 (98%) were finalised Out of the 4 474 finalised, 3 186 (71%) were finalised within 20 working days	Target was exceeded by 1%	Improvements in implementing business processes
17. 70% health product quality complaints reports produced within 30 working days	Out of 130 health product quality complaints received, 93 (72%) reports were produced within 30 working days	Target was exceeded by 2%	Additional human resources were obtained

SAHPRA
South African Health Products Regulatory Authority

P4: Clinical & Pharmaceutical Evaluation (1)

- MedSafety App launched in April 2021 to facilitate the reporting of adverse effects following immunisation and to act as a platform for collecting adverse drug reactions for other health products going forward.
- To urgently address the decline in vaccine uptake due to public safety concerns, SAHPRA participated various awareness campaigns.



SAHPRA
South African Health Products Regulatory Authority

P4: Clinical & Pharmaceutical Evaluation (2)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
18. **85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours**	Out of 16 436 applications for the sale of unregistered Category A (human) medicines received, 9 385 (57%) were finalised within 24 working hours	Target was missed by 28%	PowerApps portal does not reflect the correct submission / re-submission dates and insufficient technical staff to manually record the correct re-submission dates whilst ensuring quick turnaround times for finalisation of applications
19. **80% human clinical trial applications finalised within 90 working days**	Out of 274 human clinical trial applications received, 248 (91%) were finalised Out of the 248 finalised, 235 (95%) were finalised within 90 working days	Target was exceeded by 15%	COVID-19 trials protocols received were prioritised
20. **70% reports on health product safety signals issued within 40 working days**	Out of the 235 applications received, 95 (40%) reports were issued, of which 66 (28%) were issued within 40 working days	Target was missed by 42%	Lack of human resources and appropriate training
21. **4 safety awareness webinars held**	13 safety awareness webinars were held	Target was exceeded by 9	COVID-19 vaccination resulted in an increased need for safety information

SAHPRA
South African Health Products Regulatory Authority

P5: Medical Devices & Radiation Control (1)

- Stakeholder engagements increased
  - 3 workshops held on public comments on regulations for medical devices.
  - Contributed on guidance documents using platform such as the African Medical Device Forum, of which SAHPRA is co-chair.
  - Part of the World Health Organization Global Model Regulatory Framework Working Group for medical devices
  - Engaged with the Department of Minerals and Energy and the National Nuclear Regulator on co-regulation framework.

SAHPRA
South African Health Products Regulatory Authority

P5: Medical Devices & Radiation Control (2)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
22. 70% medical device establishment licence applications finalised within 90 days	Out of 1 105 medical device establishment licence applications received, 804 (73%) were finalised Out of the 804 finalised, 613 (76%) were finalised within 90 working days	Target was exceeded by 6%	Monitoring system was put in place and the closure of old applications was initiated
23. Guidelines to support the medical device registration regulations approved by the Executive Committee	19 guidelines to support the medical device registration regulations were drafted	Target was not achieved	Guidelines can only be approved once the Medical Device Regulations are approved, which are under review
24. 70% applications for radionuclide authorities finalised within 30 working days	Out of 4 740 applications for radionuclide authorities received, 3 803 (80%) were finalised Out of the 3 803 finalised, 2 747 (72%) were finallised within 30 working days	Target was exceeded by 2%	Effective monitoring tools put in place for new applications and the closure of old applications

SAHPRA
South African Health Products Regulatory Authority

P5: Medical Devices & Radiation Control (3)

ANNUAL TARGET	ACTUAL ACHIEVEMENT	DEVIATION	REASONS FOR DEVIATIONS
25. **70% licence applications for listed-electronic products finalised within 30 working days**	Out of 944 licence applications for listed-electronic products received, 934 (99%) were finalised Out of the 934 finalised, 924 (99%) were finalised within 30 working days	Target was exceeded by 29%	Well established business processes resulted in the efficient processing of applications
26. **Board approved Co-Regulation Model with the National Nuclear Regulator**	Terms of Reference with the National Nuclear Regulator was signed Draft Cooperate Governance and Co-Regulation Recommendation were developed	Target was not achieved	Further work had to be undertaken to strengthen the initial Co-Regulation Recommendation and the unavailability of members to attend meetings

SAHPRA
South African Health Products Regulatory Authority

Levels	FEMALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	2	-	-	-	-	-	1	-
Senior management	6	-	-	-	1	-	1	-
Professional qualified	68	-	8	-	13	-	4	-
Skilled	17	-	3	-	2	-	1	-
Semi-skilled	37	-	4	-	2	-	5	-
Unskilled	0	-	-	-	-	-	-	-
Community service	2	-	-	-	-	-	-	-
Subtotal	132	0	15	0	18	0	12	0

Levels	MALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	1	-	-	-	-	-	1	-
Senior management	3	-	1	-	1	-	-	-
Professional qualified	44	-	2	-	-	-	3	-
Skilled	3	-	-	-	-	-	-	-
Semi-skilled	33	-	3	-	-	-	1	-
Unskilled	0	-	-	-	-	-	-	-
Community Service	1	-	-	-	-	-	-	-
Subtotal	85	0	6	0	1	0	5	0
TOTAL	217	0	21	0	19	0	17	0

- Majority of employees (61%) are female and in professional qualified level.
- Employment equity target not set for 2021/22 as the organisation will implement 3-year Employment Equity Plan from 2022/23.
- No declared disabilities during the period.

SAHPRA
South African Health Products Regulatory Authority

FINANCIAL INFORMATION
AGSA Opinion (1)

Description	2021/22	2020/21	2019/20	2018/19
Audit opinion	**Unqualified**	1 Revenue Qualification	2 Revenue Qualifications	2 Revenue Qualifications
				1 Expenditure Qualification
Material Non Compliance	**1 Procurement**	2 Procurement	1 Procurement	5 Procurement
	1 AFS adjustment	1 AFS adjustment	1 Record keeping	1 Record keeping
	1 Revenue Management		1 AFS adjustment	1 AFS adjustment

Progress made:

- Unqualified audit option obtained for 2021/22 FY
- Significant reduction in the number of revenue findings raised compared to previous years
- Majority of irregular expenditure was detected by SAHPRA internal controls and disclosed
- Condonation of irregular expenditure obtained from National Treasury with reduction of year on year irregular expenditure balance.

SAHPRA South African Health Products Regulatory Authority

AGSA Opinion (2)

AUDIT REPORT FINDINGS	CORRECTIVE MEASURES
ANNUAL FINANCIAL STATEMENTS, PERFORMANCE AND ANNUAL REPORTS The financial statements submitted for auditing were not prepared in accordance with the prescribed financial reporting framework and supported by full and proper records, as required by section 55(1)(a) and (b) of the PFMA	Data validation checks to be performed on data provided to calculate total expenditure to date. Detailed reviews of outstanding commitment amount by financial year end Service in kind supporting evidence to be obtained from 3rd parties Service in kind supporting evidence detailed review and aligned to SAHPRA financial year and exchange rates
EXPENDITURE MANAGEMENT Effective and appropriate steps were not taken to prevent irregular expenditure amounting to R3 009 867, as disclosed in note 37 to the annual financial statements, as required by section 51(1)(b)(ii) of the PFMA. The majority of the irregular expenditure was caused by variations to a contract that was not approved by the relevant authority	Workshop of established policies and procedures with contract managers Consequence management implementation for non-adherence to established policies and procedures
REVENUE MANAGEMENT Effective and appropriate steps were not taken to collect all revenue, due as required by section 51(1) (b)(i) of the PFMA	Confirmation of payment step before commencement of work Review of supporting documents for payment verification and allocation Update available databases with recent client, license and or product information Allocate payments for 2022/23 and update relevant database

SAHPRA
South African Health Products Regulatory Authority

Irregular Expenditure

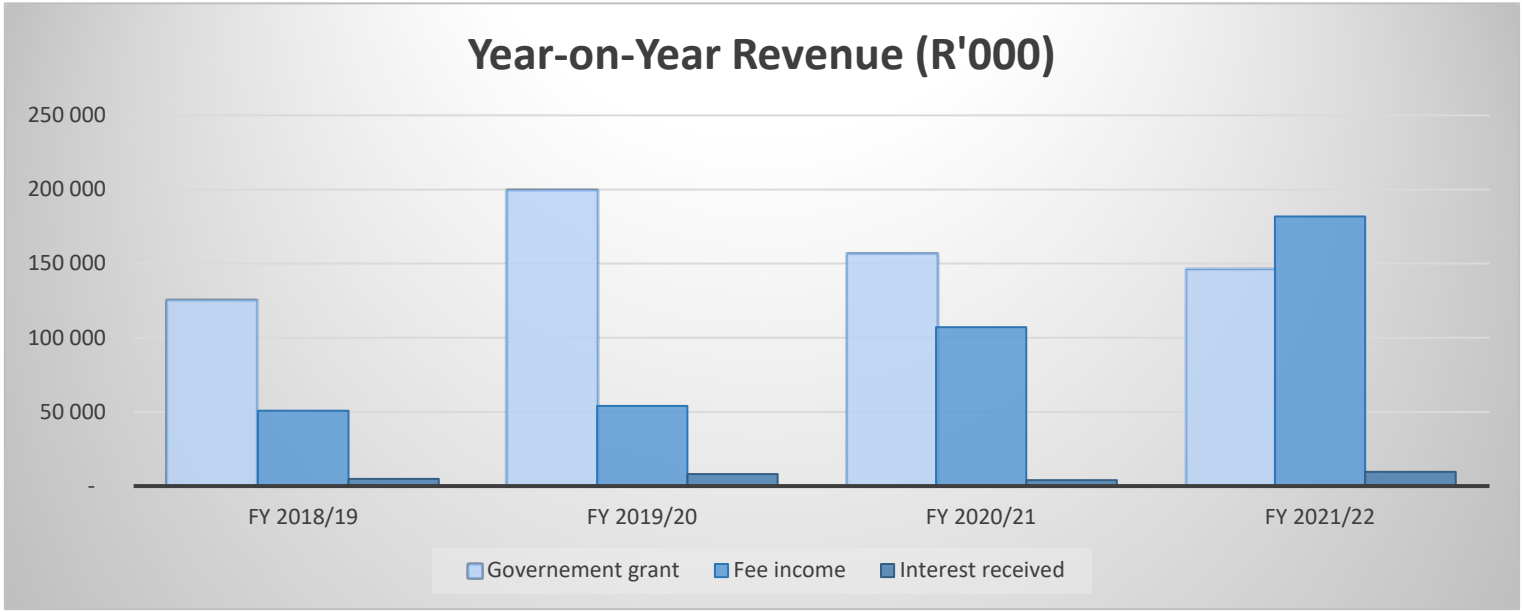
Irregular Expenditure - 2021/22	31-Mar-22	31-Mar-21
Opening Balance	10 369 881	5 038 900
Add: FW - Current Year	3 009 868	6 268 808
Add: FW - Previous Year	-	-
Less: Amounts Condoned/Removed	(10 369 881)	(931 493)
Less: Amounts Recovered	(12 750)	-
Less: Amounts incorrectly Classified		(6 335)
	3 009 867	**10 369 881**

Progress made:

- The high balance as at 31 March 2021 related to previously raised Irregular Expenditure not addressed and new transgressions identified
- The majority of the new irregular expenditure raised related to the variance of a contract relating to an ongoing legal dispute
- Since May 2021 National Treasury condoned R10.4 million after following appropriate consequence management processes
- The remaining R3 million relates to 3 transgressions for which the consequence management process is underway and expected to be finalised before March 2023.

SAHPRA
South African Health Products Regulatory Authority

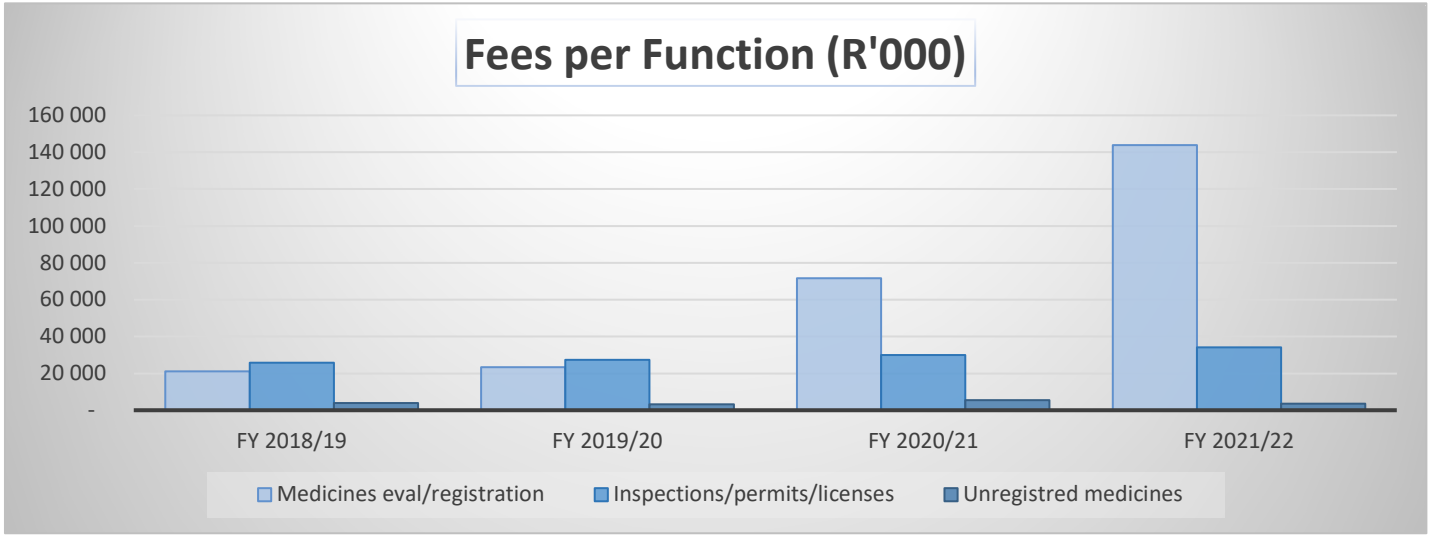
Finance (1)



- Own fee income generation exceeding government transfers for the 1st time
- Increase of fee income from R107 million (2020/21) to R181 million (2021/22)
- Interest revenue generated due to investments made in the Corporation of Public Deposits as mandated by National Treasury.

SAHPRA
South African Health Products Regulatory Authority

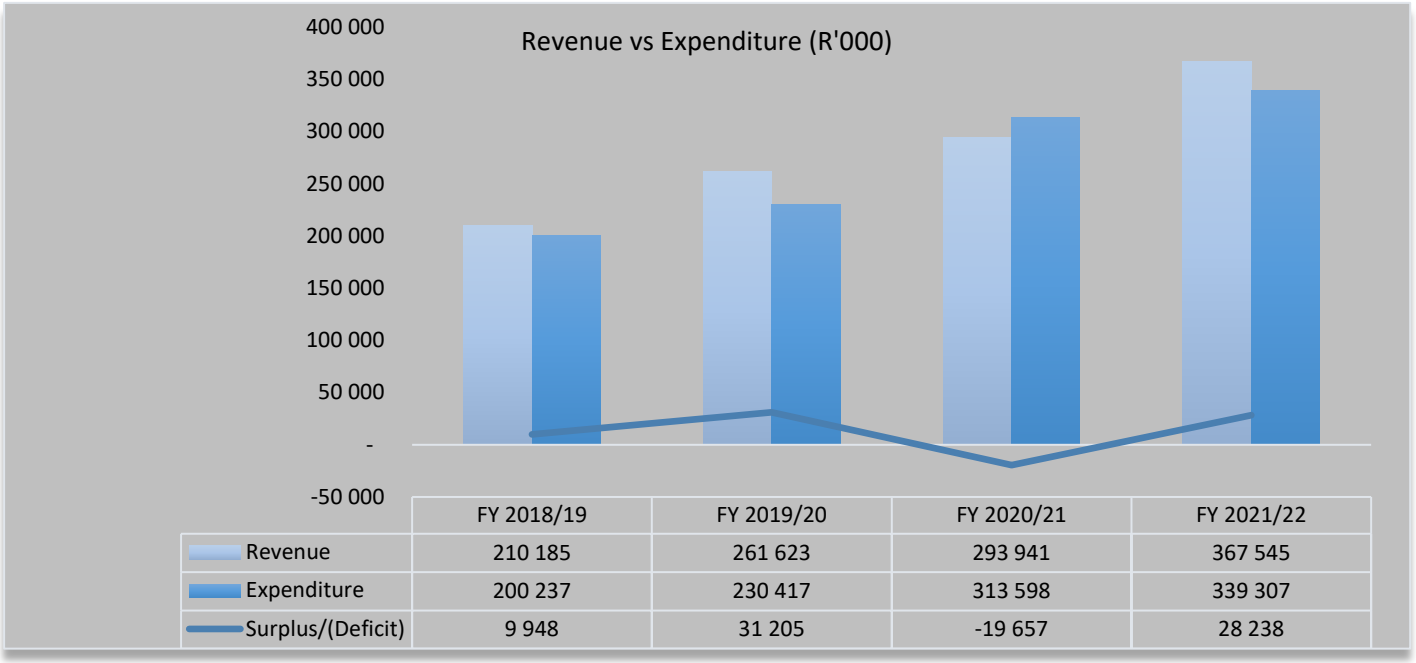
Finance (2)



- Increased own fee income generation was noticed over all per function with the exception of unregistered medicines
- The significant increase related mainly to medicine evaluations and registrations that can been completed

SAHPRA
South African Health Products Regulatory Authority

Finance (3)

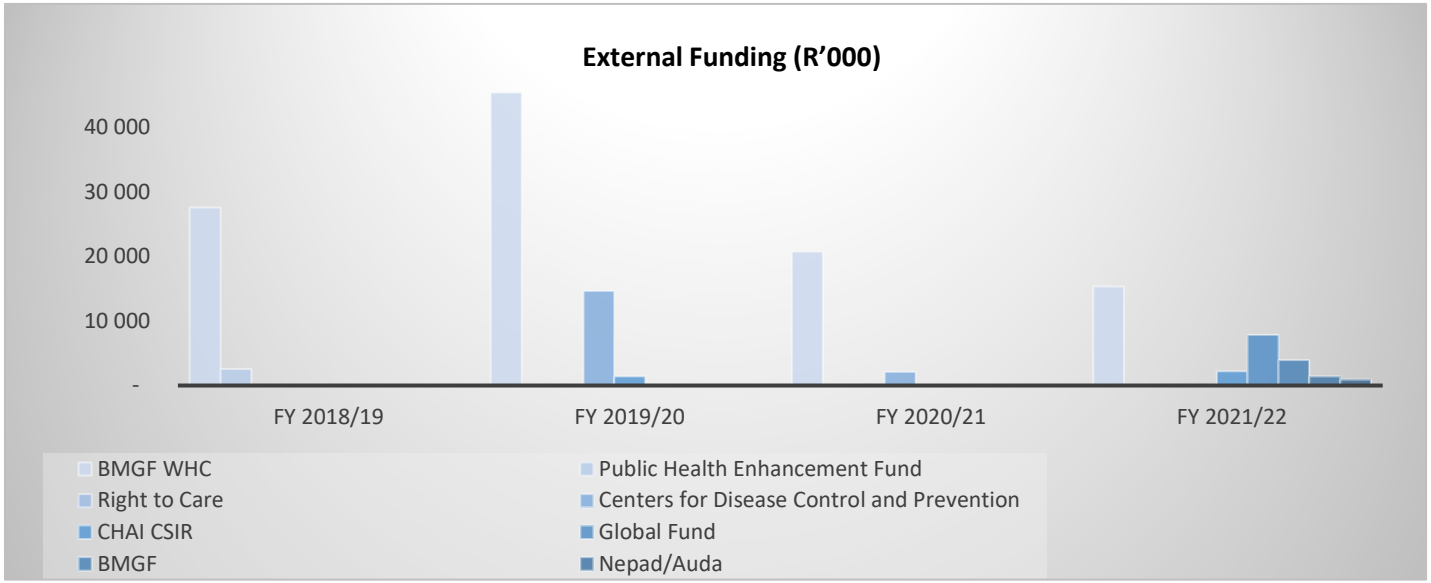


	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22
Revenue	210 185	261 623	293 941	367 545
Expenditure	200 237	230 417	313 598	339 307
Surplus/(Deficit)	9 948	31 205	-19 657	28 238

- The surplus for the 2021/22 year was mainly due to a combination of increased own revenue generation and general under expenditure
- As at the end of the 2021/22 financial year SAHPRA reported accumulated surpluses amounting to R53.6 million due to the remaining backlog funding and year on year accounting surpluses
- The majority of SAHPRA's year end liabilities relate to income received in advance which will be recognized as revenue as and when stages of services rendered are completed.

SAHPRA
South African Health Products Regulatory Authority

Finance (4)



- External funding received is mainly to fund for the backlog project.
- AUDA-NEPAD: strengthen safety monitoring systems for vaccines
- CHAI: healthcare professionals Covid vaccine data analytics.

SAHPRA
South African Health Products Regulatory Authority

Conclusion

- Achievements were made under the background of limited human resource capacity.
- Based on the increased number of applications received on a yearly basis, operations are severely constrained and require funding for optimal business operations.
- Attention is being paid to legal challenges on SAHPRA's decisions.
- SAHPRA has commenced with reviewing the Medicines Act to align with the current environmental context.
- Concerted efforts to increase public engagements especially on COVID-19 related matters, reassured the public that SAHPRA makes science-based decisions.
- SAHPRA is a young institution that has many more challenges ahead of it
  - Includes the development of appropriate oversight for medical devices, complementary medicines, cannabis and radiation control
  - Emerging issue of 'One Health' that addresses the interface between animal and human health is another priority area for SAHPRA.

SAHPRA
South African Health Products Regulatory Authority

Thank You

SAHPRA
South African
Health Products
Regulatory Authority