SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

SAHPRA's Annual Performance Plan: 2019-2020

Presentation to Portfolio Committee

04 SEPTEMBER 2019

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Our aim: Core pillars of medicine regulation and elements of an effective regulator

Independent Medicine Regulatory Authority: transparent, accountable and acts in the public interest

Focus on:

- Registration and control of medicines and good regulatory practice and standards
- Compliance with requirements
- Inspections and Law Enforcement
- Sanctions and penalties
- Information and confidentiality
- Promotions, advertising and ethical conduct
- Collaborate with tertiary institutions to support in-house capacity, capabilities and expertise

SAHPRA's vision and mission

Vision

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

Mission

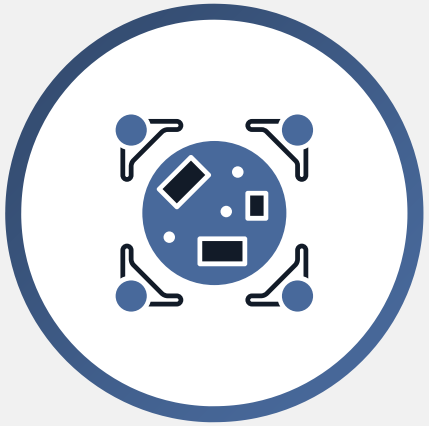
To safeguard the health and wellbeing of all who live in South Africa and to support human and animal health through scientific and ethical regulation of medicines, medical devices, radiation emitting devices and radioactive nuclides

Year 1 – 2018/2019: SAHPRA's journey

- SAHPRA was established in terms of the Medicines and Related Substances Act (Act 101 of 1965), as amended, to replace the MCC
  - It is a Schedule 3A public entity
- SAHPRA's mandate was expanded to include: regulation of all medicines including complementary medicines, medical devices and IVDs, radiation emitting devices and radioactive nuclides
- The Minister of Health appointed the SAHPRA Board on 2 October 2017
  - Board Committees: Finance, Risk, Audit and Governance, HR and Remuneration, IT, Technical Oversight and Regulatory Strategy, Communication
- The Acting CEO was appointed by the Board
- The staff transfer agreement was signed in October 2018 (section 197)
- SAHPRA started operating on 1 February 2018 with its first Board meeting
- The 2018/19 performance year represented SAHPRA's first year as a public entity
  - It was a year of transition: SAHPRA commenced work as an independent body, retaining collected revenue

SAHPRA faced multiple challenges upon launch in February 2018

Finding fit-for-purpose building



Progressing the appointment of a new Executive Team

Nearing finalisation of Section 197 transfer of staff

Dramatic re-engineering / automation of Section 21 processes

Year 2 – 2019/2020: SAHPRA's journey

- 2019/2020 is the second year of the transition period
  - SAHPRA is busy with capacity building so it can perform at its full potential
- SAHPRA inherited an operational but partially capacitated core business
  - SAHPRA had to also establish its own corporate services capabilities
- SAHPRA will take up to 3 - 5 years to realise its full potential
- A balanced approach was needed to address both the operational difficulties of the entity derived from the medicines backlog and newly adopted functions of the medical devices and radiation control functions, while simultaneously growing a brand new corporate services programme

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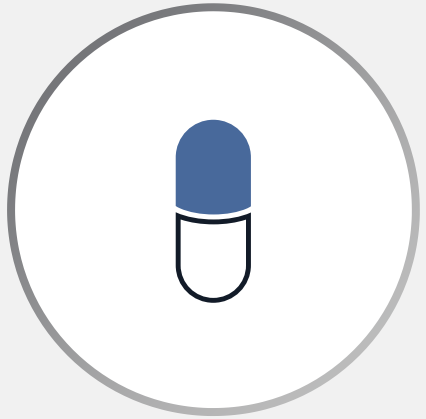
SAHPRA's policy mandate



Regulation of health products intended for human and animal use

Licensing of manufacturers, wholesalers and distributors of medicines and medical devices, radiation emitting devices and radioactive nuclides

Conduct of clinical trials in a manner compatible with the national medicines policy

SAHPRA's legislative mandate

The Constitution of the Republic of South Africa, 1996

The National Health Act, 2003 (Act No. 61 of 2003)

The Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended

Hazardous Substances Act (Act No. 15 of 1973)

Public Finance Management Act, 1999 (Act No. 29 of 1999)

Other related legislation impacting on and influencing the functioning of SAHPRA

Constitutional mandate

The Constitution places obligations on the State to progressively realise socio-economic rights, including access to health care.

Section 27 of the Constitution guarantees everyone the right of access to healthcare services:

- Everyone has the right to have access to
  - Health care services, including reproductive health care;
  - Sufficient food and water;
  - Social security, including, if they are unable to support themselves and their dependents, appropriate social assistance
- The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights
- No one may be refused emergency medical treatment

SAHPRA's legislative mandate: National Healthcare Act

Provides a framework for a structured uniform health system, taking into account the obligations imposed by the Constitution and other laws on government.

Key objectives of the National Health Act (NHA) that impact the work of SAHPRA include:

- Unite the various elements of the national health system to promote and improve the national health system in South Africa
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognized standards of research and a spirit of enquiry and advocacy which encourage participation
- Promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans

SAHPRA's legislative mandate: Medicines and Related Substances Act

Section 2B (1) of the Medicines Act requires the Authority to ensure:

- Efficient, effective and ethical assessment and regulation of health products that meet defined standards of quality, safety, efficacy and performance;
- Transparent, fair, objective and timeous assessment and registration;
- Periodic re-evaluation or re-assessment and ongoing monitoring of products in the marketplace;
- Investigation and monitoring of existing and new adverse events and reactions, interactions, and signals emerging from post-marketing surveillance;
- Compliance through active inspections and investigation; and
- Assessment of clinical trial or clinical performance study protocols according to prescribed scientific, ethical and professional criteria and defined standards.
- In executing its functions, the Authority may enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

SAHPRA's legislative mandate: Hazardous Substance Act

Within the Medicines Act, “medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)

The Hazardous Substances Act provides for the efficient, effective and ethical evaluation and registration of non-ionizing radiation emitting devices and radioactive nuclides.

It also prohibits and controls the importation, manufacture, sale, use, operation, application, modification, disposal or dumping of substances and (electronic) products that may cause injury or death due to their detrimental effects.

Any substance or mixture of substances which, in the course of reasonable handling might, by reason of *its* toxic, corrosive, irritant, strongly sensitizing or flammable nature or because it generates pressure through decomposition, heat or other means, cause injury, ill-health or death to human beings, to be a Group I or II hazardous substance

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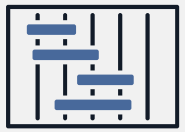
SAHPRA's governance

The Minister of Health appointed a board in terms of the Act

Currently, an Acting CEO is appointed; Recruitment of a permanent CEO and other Executives is underway



Management is in place to run the day to day business of the organisation

The Board has approved the macro-organisational structure which is currently being capacitated.

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Medicines: Registration of pharmaceutical and biological products

Overview

SAHPRA has been able to make significant progress in a number of key areas in spite of some of its challenges:

- In 2018/19 SAHPRA, developed a comprehensive, costed Backlog Clearance Strategy for human, veterinary pharmaceutical and biological products
- New and efficient digital tools introduced for routine evaluations going forward including reliance mechanisms that take account of other international regulatory approvals following the backlog clearance project
- Evaluation of Medicines required for HIV, TB and cancer, New Chemical Entities (NCE) and biological medicines prioritised through expedited review
- Designed a new fees & performance metrics model for human pharmaceutical and biological products
- Digitised and automated a number of processes within Registration (eCTD) and Section 21 units
- Completed an audit of pending and in-process clinical trial applications to objectively assess if there is an immediate crisis that threatens human life or academic research

These efforts lay the foundation to begin establishing an effective, efficient and sustainable Regulator from 2019-20

Medicines: Registration of pharmaceutical and biological products

Key Objectives for 2019-2020 (I/II)

1. Roll-out the Backlog Clearance Program
2. Roll-out the new evaluation models designed for the backlog clearance program for ‘business as usual’ (BAU)
3. Implement the inflationary fees already published for public comment, with one notable change being an increase of annual retention fees to R2 200 per product
4. Implement the second phase of the new fees & performance metrics model by September 2019
   - These are focused on quick wins related to services not currently attracting fees, and where fee increases can be easily justified
5. Ongoing industry engagement to complete application and GMP surveys
6. Publish new regulations and guidelines for comment to facilitate reliance models

Medicines: Registration of pharmaceutical and biological products

Key Objectives for 2019-2020 (II/II)

7. Conduct multiple training and information sessions regarding new policies and processes to relevant stakeholders

8. Finalising all internal and external documents, and refining processes based on pilot experiences

9. Recruitment of the necessary human resources

10. Train staff on the new application evaluation pathways, document management and workflow support solutions

11. In addition to this work on the Backlog Clearance Program, SAHPRA will define and implement a strategy to leverage the new models of evaluation for BAU
    - There will need to be regular communication with industry and other public health stakeholders
    - Furthermore, there will be widespread training and upskilling of all current SAHPRA staff

Sale of unregistered medicines: Section 21 applications

Overview

- SAHPRA's Section 21 Unit evaluates applications for access to emergency, unregistered medicines in life-threatening situations – both for individual patients and for hospitals
- During 2018-19 a comprehensive analysis of Section 21 processes was conducted to identify areas needing improvements. Various challenges were identified:
  - The application process was inefficient, with significant time spent on administrative tasks, such as data capture and letter creation;
  - ~50 % of applications were for renewals, which required the same amount of work as new applications

Key achievements in 2018-19

- To address these challenges, SAHPRA introduced an online application process, which dramatically re-engineered the former process:
  - This greatly reduced the time required for the approval process, allowing two staff members to keep up with the daily volumes of ~110 incoming applications (including backlog resubmissions). The Section 21 backlog was cleared by November 2018

Sale of unregistered medicines: Section 21 applications

Key Objectives for 2019-2020

1. Additional work will be undertaken on the digital systems to ensure that they optimally support the evaluation process of Section 21

Clinical trials

Overview

- A thriving clinical trials sector in South Africa is an important contributor to clinical and academic research expertise and local health product development
- SAHPRA's Clinical Trials Unit reviews four types of submissions:
    1. New authorisations (pharmaceutical industry trials, academic trials, bioequivalence studies): evaluated on a two-month cycle
    2. Protocol amendments
    3. Investigator and site (I&S) amendments
    4. Notifications
- As of 14 December 2018 there were 175 clinical trial applications to be completed:
    - 35 new authorisation applications were in-process, with another 30 applications due for evaluation in the January 2019 cycle
    - 96 protocol amendments were in-process
    - 11 investigator and site (I&S) amendments were in-process
    - Improvements can be implemented to prevent a significant backlog developing. These improvements will be the strategic focus in 2019-20

Clinical trials

Key Objectives for 2019-2020

1. To clear the backlog, and to prevent Clinical Trials from entering a crisis state, the unit will be assigned additional administrative and clinical staff

2. In order to reassure industry and academic applicants, SAHPRA will regularly communicate the status of the Clinical Trials unit, for clearing the backlog

3. SAHPRA will also investigate and potentially procure a digital workflow/online application system for Clinical Trials
   - This will enable automated data capture into databases, easy tracking of application status, and minimise basic administrative errors

Inspections, licensing and regulatory compliance

Overview

- The inspectorate, licensing and regulatory compliance arm of SAHPRA ensures that the pharmaceutical premises, personnel and medicinal products meet the minimum standards of Good Manufacturing, Wholesale and Clinical practice and function within the ambit of the Medicines Act and regulations through regular and scheduled inspection activities
- The unit has consistently met its mandate, and is under no immediate crisis.
- A natural consequence of change has resulted in higher attrition rates of staff, with a number of staff being poached from the industry stakeholders
  - Stabilising staff capacity and competency to meet the expanding mandate to support eradication of the registration backlog is a key area of focus for licensing and inspections

Inspections, licensing and regulatory compliance

Key Objectives for 2019-2020

1. The unit will continue receiving new applications and continue with further inspections. There will be reconciliation of the application fees as well as the inspection fees

2. Staffing for both capacity and competency will be prioritised so as to prevent any development of a backlog in this unit

3. An area of particular focus for the expansion of staffing for both capacity and competency must support the focus to strengthen border control

4. The move of the entity towards digitised pathways and processes will also be a key focus of this unit with the intention of increasing current output

Medical devices

Overview

- The medical device unit is responsible for the licensing of manufacturers, distributors and wholesalers of medical devices, facilitating the evaluation of medical device clinical trial applications, investigating and responding to law enforcement activities and section 36 exemptions related to medical devices, management of medical device vigilance reports and supporting the medical device committee
- In 2018/2019 the Medical Device Unit was staffed with a Deputy Director, two community service pharmacists and one administrative staff member who assisted the unit on a part-time basis
  - Despite limited staffing the unit was able to licence approximately 700 medical device facilities
- A large number of stakeholder engagements for information sharing and education and consultation on the road map for registration was held in 2018. This has brought this road map to readiness for Board approval which will be imminent in 2019

Medical devices

Key Objectives for 2019-2020

1. Implementation of a system to register medical devices
2. Increased staffing to support expanded registration and safety monitoring framework
3. The implementation of a specialised IT system to complement the activities of the Medical Device Unit has been identified as a performance area for 2019/2010
4. The development of an online system for registration of medical devices

Radiation control

Overview

- A new functional area of SAHPRA responsibilities is the regulation of all electro medical devices and sources emitting ionising radiation.
  - Staff in the NDoH Radiation Control Unit responsible for this mandate were transferred to SAHPRA in October 2018
- Regulatory functions of Radiation Control unit include licensing, compliance management, enforcement, investigation of complaints and incidents/accidents involving ionizing radiation, occupational exposures, import-export, disposal, etc. Regulation of devices involves validation and registration of devices that emit ionizing of non-ionizing radiation used in medical and industrial applications. It also involves devices, which contain radioactive sources
- These products are categorized into two groups, namely Group III and Group IV as defined in the Hazardous Substances Act
- Radiation Control is experiencing curtailment of its regulatory functions due to critical staff shortages that persisted over many years

Radiation control

Key Objectives for 2019-2020

1. SAHPRA has prioritised capacitation of the unit

2. A further consideration is that this is now the only unit of SAHPRA that has to-date not charged fees for the services provided
   - A working group was assembled in 2018 to review the situation and advise and changes to this fee for service infrastructure are envisaged for the future of this unit within the entity
   - Their recommendations will be reviewed for implementation in 2019

3. As this is a new portfolio for SAHPRA, there is a need for the Authority and the National Department of Health to converse with the relevant stakeholders, including the National Nuclear Regulator and the Department of Energy

Corporate services

Overview

- SAHPRA's first year as a fledgling entity was marked by protracted protest action that hindered the administrative support within SAHPRA's own structures as well as that which should have been received in accordance with the Memorandum of Agreement signed with the NDoH
- This was compounded by difficulties with SAHPRA accommodation, necessitating an urgent relocation to keep SAHPRA functional
- Capacitation of the organisation's executive and senior management echelon began in 2018 and is ongoing in 2019
- Staff Transfer Agreements signed in October 2018: Section 197 and staff formally notified of transfer in October 2018

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A critical first task for SAHPRA was the clearance of the inherited medical products backlog, defined as:

> All applications[1] submitted which are yet to receive final approval (including certification), as of 31 January 2018[2]

1. Includes duplicates, clones, multiple doses and multiple dosage forms 2. SAHPRA was formed on 1 February 2018

Top facts about the inherited backlog

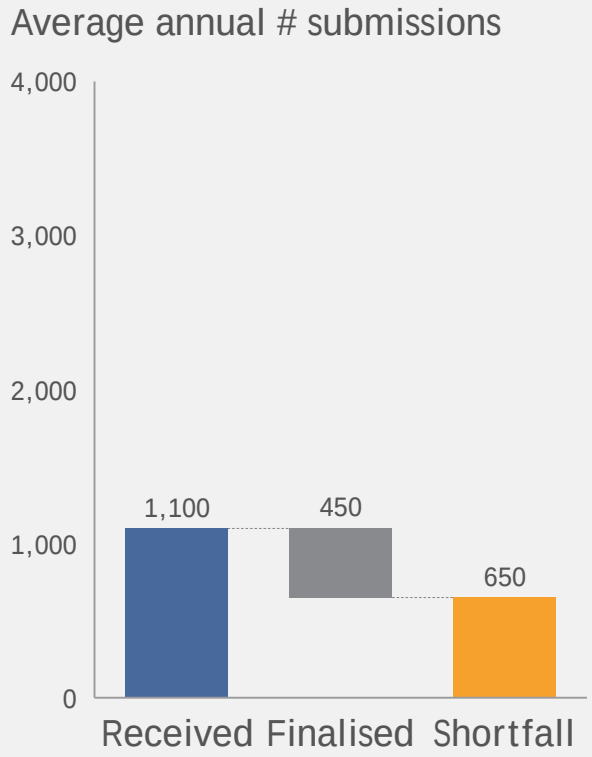
~16,000
applications
(50% new registration & 50% variations)

1992
Submission year of the oldest backlog application

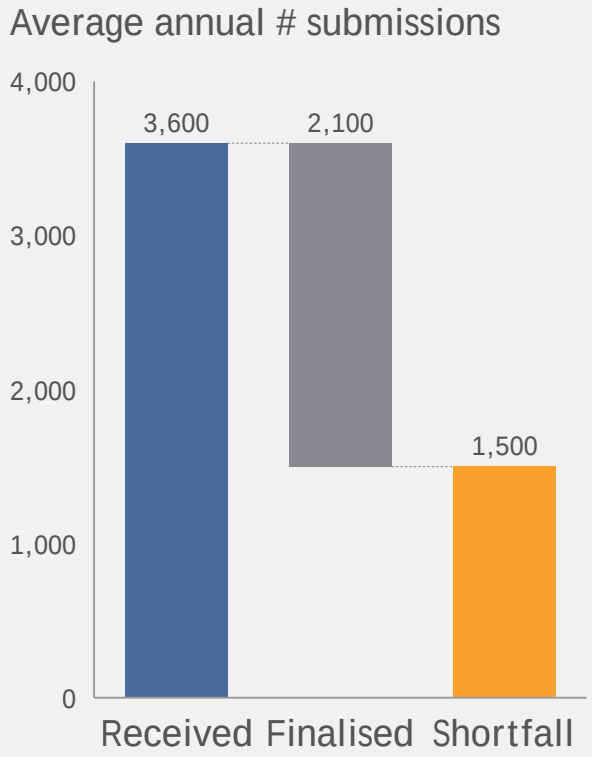
50%
New registration backlog applications older than 5 years (2013)

In addition to the inherited backlog, SAHPRA receives 4,700 applications per year, but only processes 2,550

Pre-registration



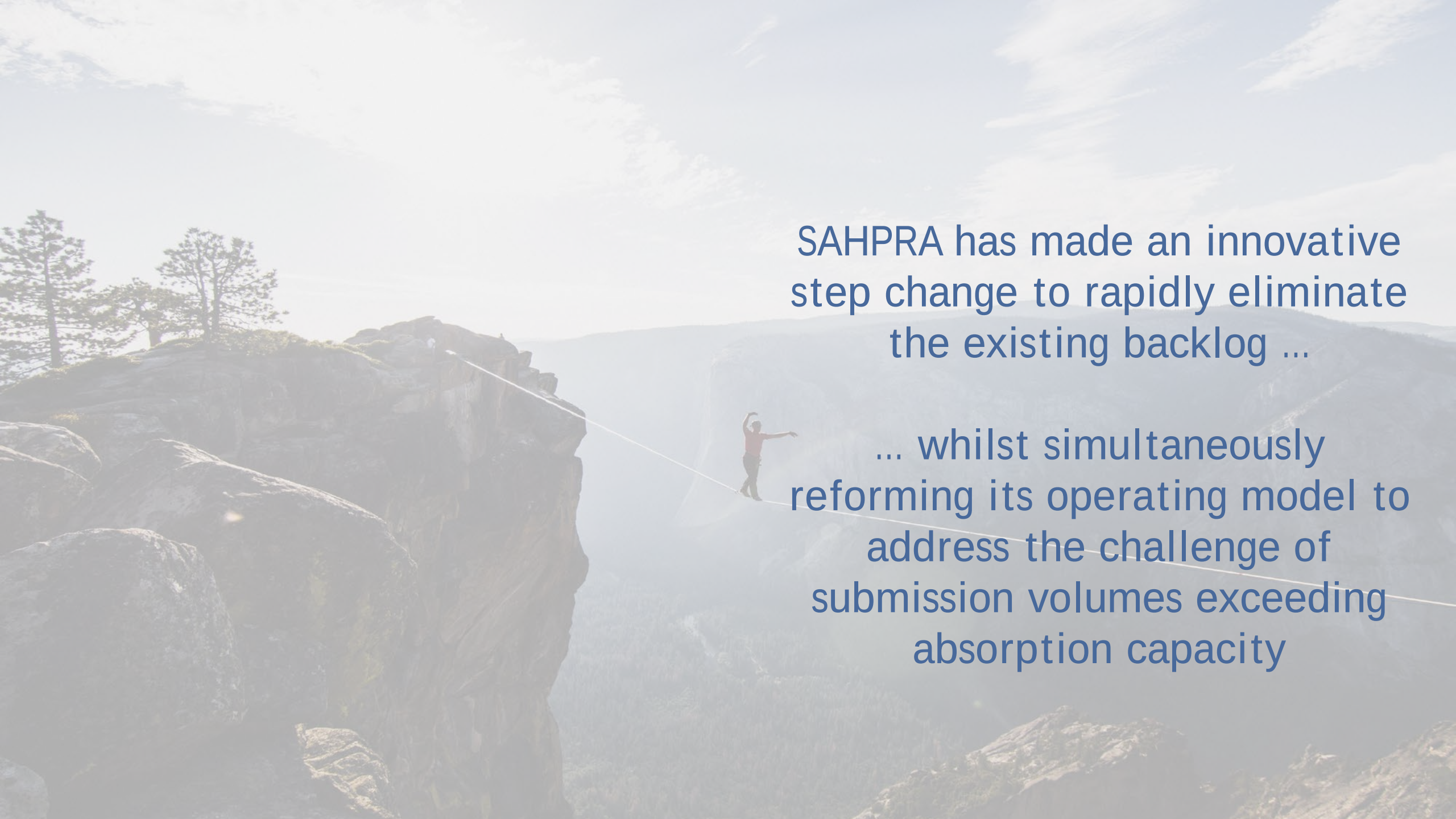
Post-registration



The backlog is not just an historical problem; it is an ongoing challenge

Source: SAHPRA team interviews; team analysis


At current capacity and with current processes, it would take SAHPRA **8 years** to clear the backlog – assuming no new applications



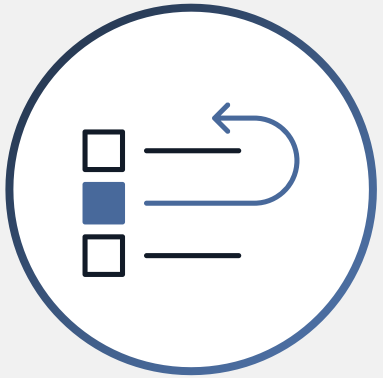
SAHPRA has made an innovative step change to rapidly eliminate the existing backlog …

… whilst simultaneously reforming its operating model to address the challenge of submission volumes exceeding absorption capacity


The ambition of the SAHPRA Board:
To clear the backlog within 2 years

Three pillars of SAHPRA's backlog clearance strategy

Reduce the number of applications that require evaluation

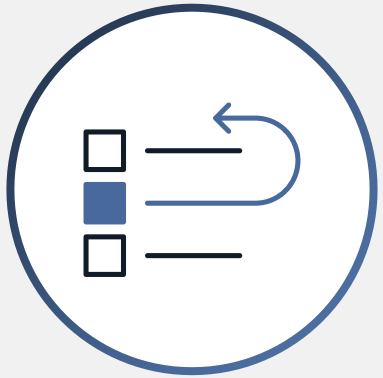


Segment and prioritise remaining applications

Design and implement new models for evaluation

Pillar 1

Reduce the number of applications that require evaluation

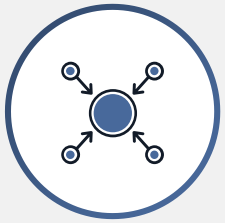


Segment and prioritise remaining applications

Design and implement new models for evaluation

We needed to reduce the number of applications for evaluation

"Opt-in" for pre-2014 new registration applications; "opt-out" for post-2014



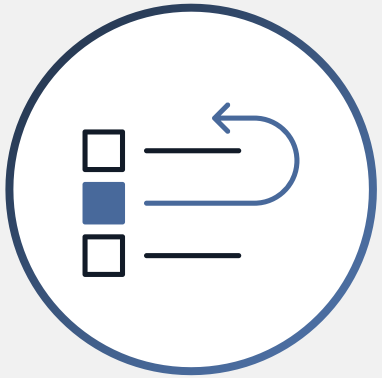
Consolidate, update, and resubmit all applications

Reject poor quality applications

As a result of Pillar 1, ~3,000 new registration applications have been withdrawn

Pillar 2

Reduce the number of applications that require evaluation



Segment and prioritise remaining applications

Design and implement new models for evaluation

Applications are grouped by therapeutic area and prioritised by public health need

Highest priority

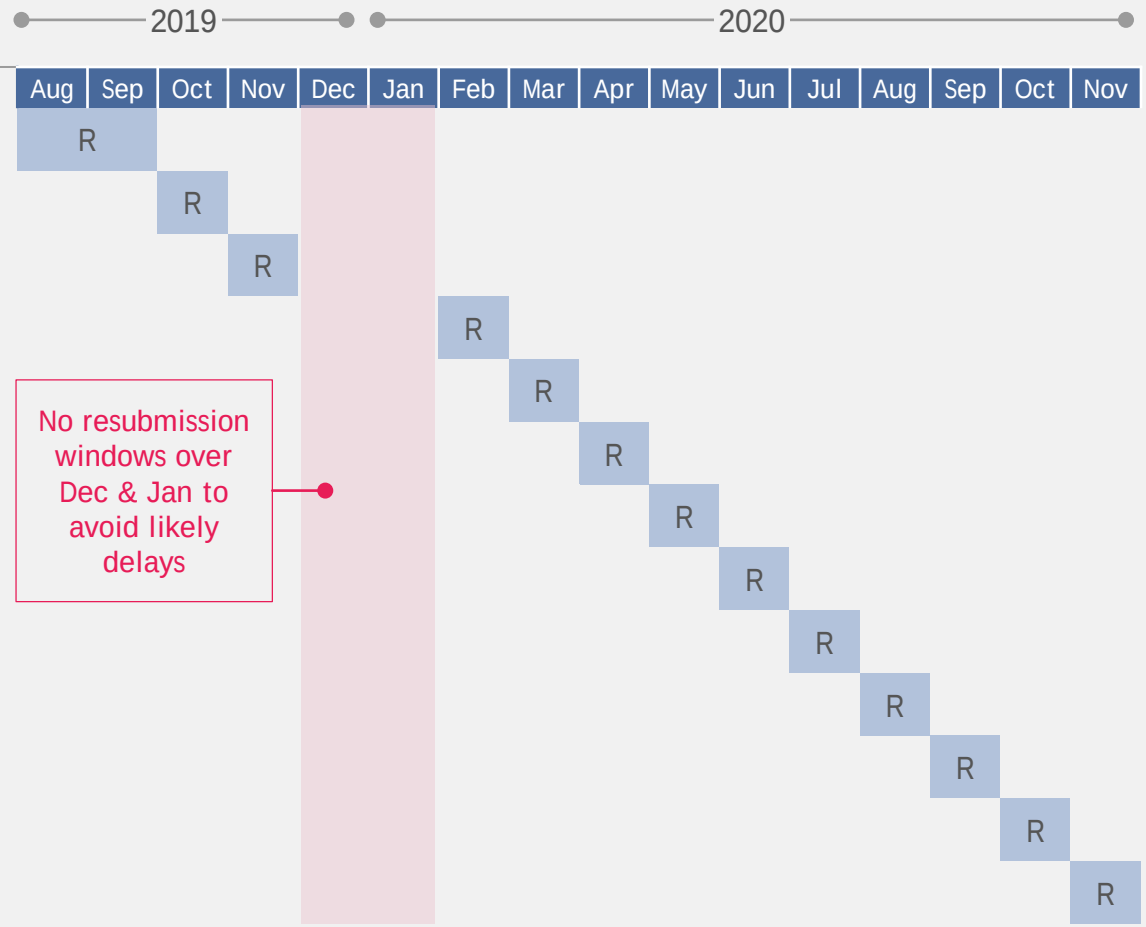
- HIV; TB; Hepatitis; Vaccines
- Oncology
- Mental and behavioural disorders
- Infectious / parasitic diseases
- Maternal and newborn health; Diabetes; Malaria
- Respiratory system diseases
- Cardiovascular disease
- Haematological / immunological diseases
- Analgesics and NSAIDs
- Genitourinary system diseases
- Nervous system diseases
- Endocrine, nutritional and metabolic diseases
- Digestive system diseases
- Musculoskeletal system and connective tissue diseases
- Skin and subcutaneous tissue diseases
- Eye and adnexa diseases; ear and mastoid diseases
- Other[1]

1. All APIs that do not fit into a designated therapeutic area, including anti-histamines and other allergy medications
Source: Application survey database, Engagement with NDoH

New registration applications will be resubmitted in specified "windows"

Resubmission window categories

1	HIV; TB; Hepatitis; Vaccines + high priority NCEs
2	Oncology + medium priority NCEs
3	Mental & behavioural disorders + low priority NCEs
4	Infectious / parasitic diseases
5	Maternal & newborn health; Diabetes; Malaria; APIs of unmet need
6	Respiratory system diseases
7	Cardiovascular disease
8	Haematological / immunological diseases; Analgesics & NSAIDs
9	Genitourinary system diseases; Nervous system diseases
10	Endocrine, nutritional & metabolic diseases; Digestive system diseases
11	Musculoskeletal system & connective tissue; Skin and subcutaneous tissue
12	Eye & adnexa diseases; ear & mastoid diseases
13	Other[1]

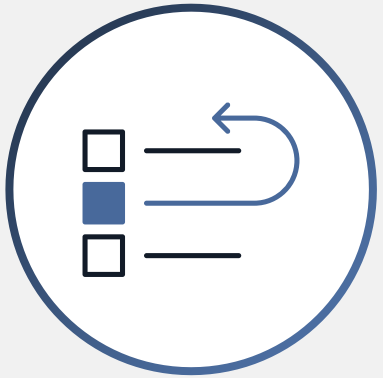


R Resubmission window Festive season

Note: Names of therapeutic areas have been abbreviated; NSAIDs = Non-steroidal anti-inflammatory drugs; 1. All APIs that do not fit into a designated therapeutic area, including anti-histamines and other allergy medications

Pillar 3

Reduce the number of applications that require evaluation



Segment and prioritise remaining applications

Design and implement new models for evaluation

The decisions of these recognised regulators will translate to new reliance policies

Full review

Conduct complete scientific review for safety, quality, efficacy, GMP

Abridged review

Assess specific, pre-agreed areas of substantive interest to SAHPRA e.g. stability data, interaction with HIV / TB medications

Verified review

Validate that application conforms to reference authorisation and provides required information[1]

Recognition

Accept reference authorisation without review

Notification

Accept company's application without review

Extent of evaluation by SAHPRA

1. Includes regional stability requirements 2. Not an evaluation policy for registration purposes 3. Safety, quality, efficacy
Source: Frontiers Pharmacology 'Comparison of Turkish regulator to TGA, HSA , SFDA and HC; Minutes of industry & SAHPRA backlog meeting 9 May

SAHPRA's new models for evaluation include reliance on the regulatory decisions of selected, globally-renowned regulatory authorities

European Medicines Agency (EMA) Centralised and Decentralised Procedure

Health Canada

Medicines and Health products Regulatory Agency (MHRA) – UK

Ministry of Health, Labour and Welfare (MHLW) – Japan

Swiss Agency for Therapeutic Products (Swissmedic)

Therapeutic Goods Administration (TGA) - Australia

US Food and Drug Administration (US FDA)

World Health Organisation (WHO) Prequalification

Zazibona Collaborative Process

In addition to new evaluation models, a new operating model is required

Staffed for success

Dedicated Backlog Clearance Team to manage the Program for 2 years, supported by SAHPRA management

Digitally empowered

All-electronic submission: Going from tonnes of paper to cloud computing

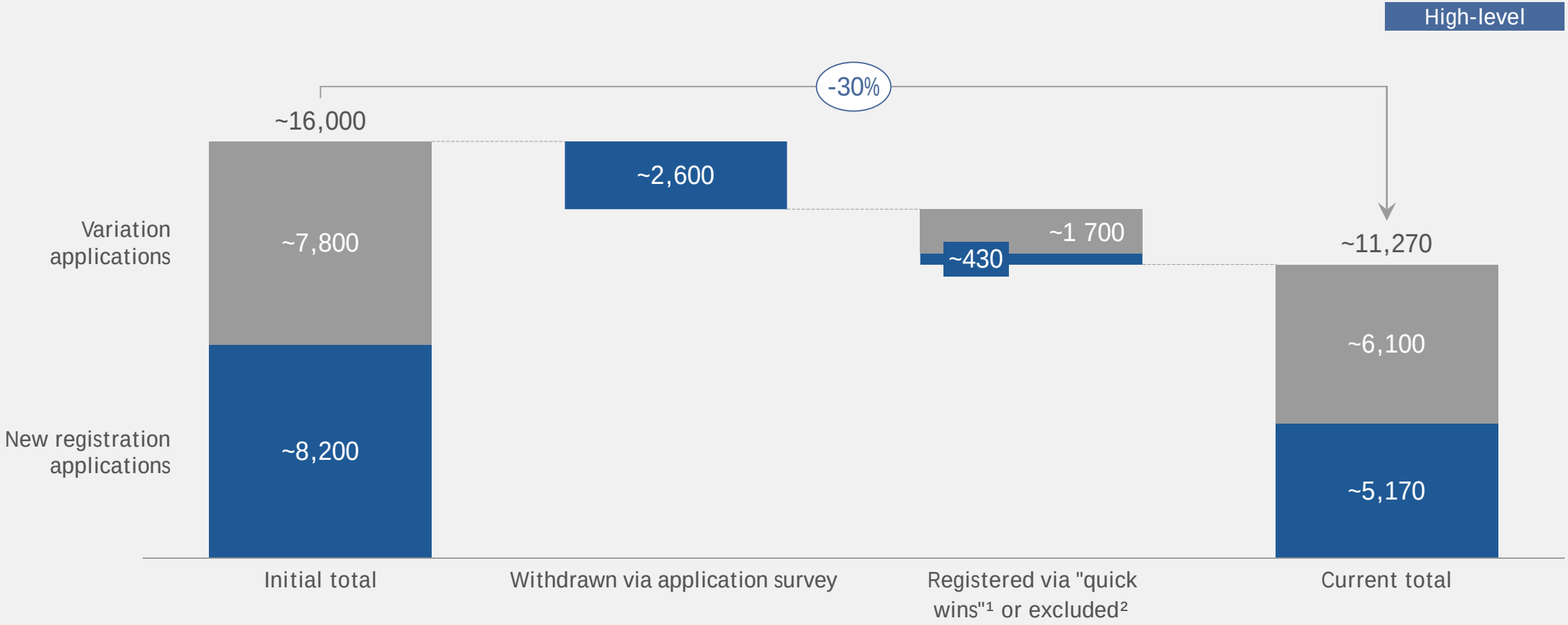
Effective program management

Regular and transparent communication with industry and other stakeholders to ensure sufficient governance

FDA = Food and Drug Administration; MHRA = Medicines and Healthcare products Regulatory Agency

Where are we today?

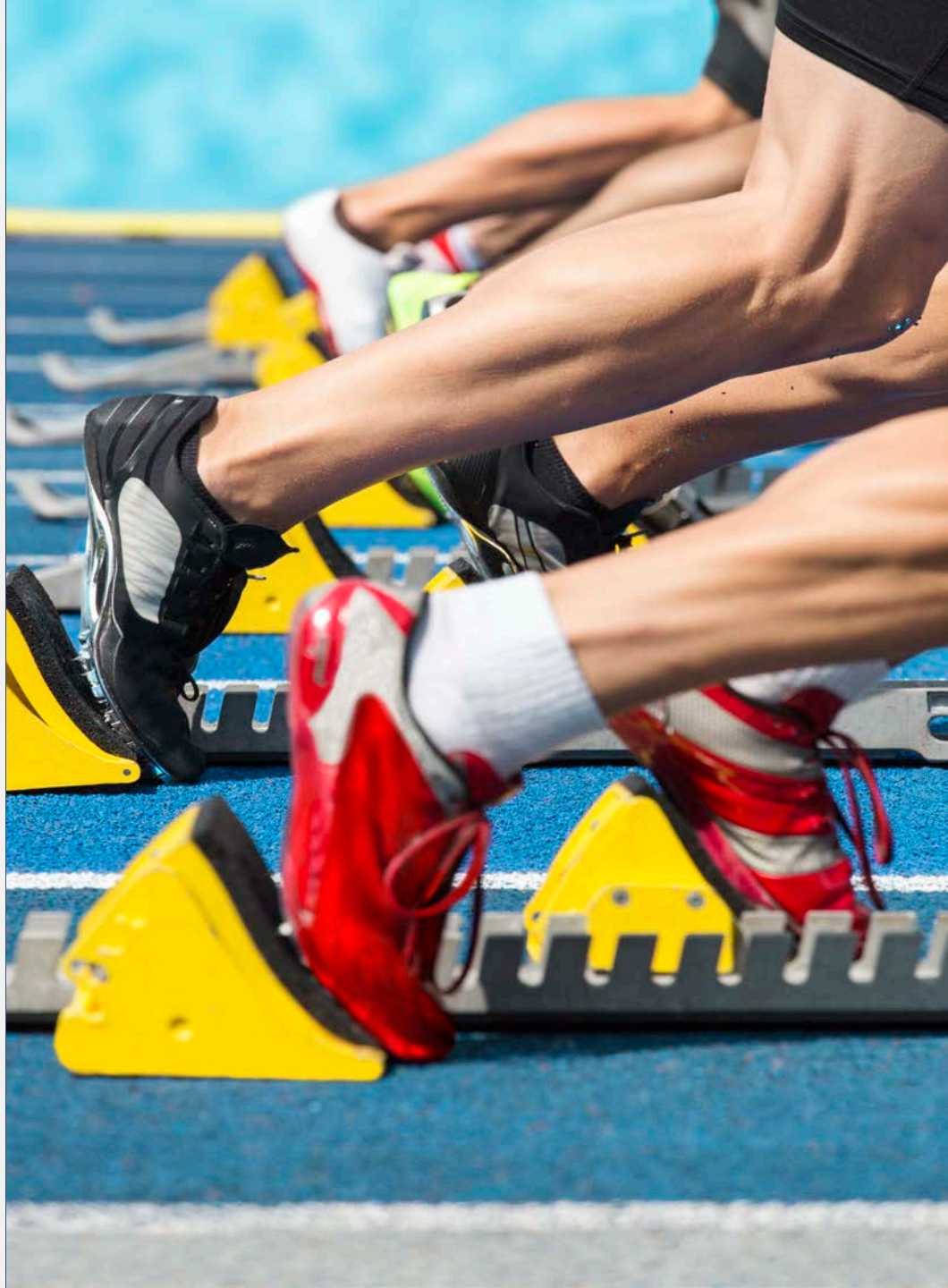
Current number of backlog applications, to be cleared over the next 2 years



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

Business As Usual (BAU)
New medicines registration and variation applications received from 1 Feb 2018 onwards

Harmonised Backlog and BAU processes

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

Ultimately, a healthy regulator benefits all South Africans

Increased access to medicines

Local job creation opportunities

Safe, effective, high quality health products

Investor confidence in South Africa's pharmaceutical industry

Health services and clinical research in line with global best practice

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Strategic outcome-oriented goals (I/III)

Goal 1:	Demonstrate responsiveness and accountability as an effective and efficient high performance organisation
Goal Statement :	SAHPRA is an effective and efficient high performing organisation that is responsive and publicly accountable.
Indicator :	Audit Outcome
Goal 2:	Timeous regulatory decisions taken on applications to ensure compliance to defined standards of quality, safety, efficacy and/or performance
Goal Statement:	Timeous regulatory decisions based on defined standards for Quality, Safety, Efficacy and Performance.
Indicator:	Regulatory decision taken within a specified timeline
Goal 3:	Re-evaluate and monitor medicines and medical devices periodically
Goal Statement:	Establish a framework to ensure that registered products are periodically re-evaluated in accordance with defined standards of Quality, Safety, Efficacy and Performance
Indicator:	Framework finalised and approved within a specified timeline

Strategic outcome-oriented goals (II/III)

Goal 4:	Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance
Goal Statement:	Ensure that evidence of existing and new adverse events, interactions, signals emerging from post-marketing surveillance and vigilance is being solicited, investigated, monitored, analysed and acted upon; and establish supportive national and global partnerships.
Indicator:	Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded.
Goal 5:	Ensure regulatory compliance through a process of active Inspections and investigations
Goal Statement:	Inspect and Investigate Establishments and permit holders in accordance with the defined guidelines and standards
Indicator:	% of Establishments inspected within specified timelines
	% of permits issued within specified timelines.
Goal 6:	Evaluate clinical trial protocols in accordance with defined standards
Goal Statement:	Clinical trial protocols are evaluated in accordance with the defined standards to ensure participant safety and data integrity.
Indicator:	% of clinical trial protocols evaluated within a specified timeline

Strategic outcome-oriented goals (III/III)

Goal 7:	Evaluate the applications for sale of unregistered health products in accordance with defined standards
Goal Statement:	Ensure that unregistered health product applications are evaluated in accordance with defined standards to ensure access only to safe, efficacious and quality unregistered health products.
Indicator:	% of applications for the sale of an unregistered health product evaluated within a specified timeline.
Goal 8:	Establish and strengthen collaborative initiatives with any other regulatory authority or institutions in order to achieve the objects of the Medicines Act
Goal Statement:	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 enter into agreements of collaboration with any regulatory authority or other relevant organisations.
Indicator:	Establish at least 9 collaborative relationships to support the functions of SAHPRA
Goal 9:	SAHPRA is capacitated by adequate, competent and motivated human capital
Goal Statement:	A functional SAHPRA with a budget and personnel to implement the Authority's mandate effectively is phased in and fully operational by 2023.
Indicator:	% of funded positions filled

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Programme One: Administration

Purpose

To provide the leadership and administrative support necessary for SAHPRA to deliver on its mandate and comply with all relevant legislative requirements.

Programme 1 has four sub-programmes:

- Sub-Programme 1: Financial and Supply Chain Management
- Sub-Programme 2: Governance and Compliance
- Sub-Programme 3: Information Technology and Communication
- Sub-Programme 4: Human Resource Management

Objectives

80% of funded positions filled on new staff establishment to ensure a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA

25% positive response to independent stakeholder surveys to ensure Stakeholder awareness of SAHPRA

90% uptime on a fully functioning information management system that permits tracking of all business activities

Updated Medicine and medical device registers published on the regulators website quarterly

Programme Two: Authorisation Management

Purpose

To provide administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements.

The purpose of this programme is to co-ordinate the process of registration and/or licensing or amendment of applications in respect of medicines within a legislative framework that defines the requirements necessary for application to the Authority, to receive, record and distribute all documents submitted to SAHPRA, to manage and maintain SAHPRA's main Registry.

There are five sub-programmes, namely:

- Sub-Programme 1: Document Reception and Helpdesk
- Sub-Programme 2: Records Management
- Sub-programme 3: Project Office – Regulatory Decision for Medicines
- Sub-programme 4: Project Office - Clinical Trials, Section 21 Portfolio Management
- Sub-Programme 5: Licensing, Permits and Certificates Portfolio Management

Objectives

40% Backlog Applications prior to 1st February 2018 with regulatory decisions taken

60% of licence issued within predefined timelines on quarterly basis

65% of permits issued within predefined timelines on quarterly basis

90% of certificates prepared for new registrations within 7 days of completed review

Programme Three: Inspectorate & Regulatory Compliance

Purpose

The main purpose of this programme is to ensure public access to safe health products through inspections and regulatory compliance. The focus of this programme includes assessment of site compliance with good regulatory practices, including:

- Good Manufacturing Practice (GMP);
- Good Clinical Practice (GCP);
- Good Warehouse Practice (GWP);
- Good Distribution Practice (GDP);
- Good Laboratory Practice (GLP);
- Good Vigilance Practice(GVP)

Conduct inspections at Active Pharmaceutical Ingredient (API), medicine and medical device manufacturers; wholesalers; laboratories; and clinical trial sites, located both locally and internationally; as well as inspection and monitoring of compliance with applicable legislation.
There are three sub-programmes, namely:

- Sub-Programme 1: Inspections
- Sub-Programme 2: Regulatory Compliance
- Sub-Programme 3: Laboratory Services

Objectives

50% of establishments due for inspection inspected annually

85% of reliance reviews completed

20% of permit holders / establishments / sites of narcotic and psychotropic substances inspected annually

40% of permit holders / establishments / sites of narcotic and psychotropic substances inspected annually

Programme Four: Medicines Evaluation & Registration

Purpose

To evaluate the safety, quality and therapeutic efficacy of medicines and register them for use as per delegated authority in terms of relevant legislation. The functions within this programme include:

- Management of the evaluation of applications to ensure safety, quality and efficacy of products.
- Management of the registration and control of medicines.
- Management of regulations pertaining to the sales of medicines.
- Establishment of surveillance mechanisms to detect, assess and prevent adverse reactions to health products.
- Management of the authorisation of sale of unregistered medicine for specified purposes in terms of relevant legislation.

There are seven sub-programmes, namely:

- Sub-Programme 1: Clinical Evaluation
- Sub-Programme 2: Clinical Trials
- Sub-Programme 3: Pharmaceutical Evaluation
- Sub-Programme 4: Vigilance and Post-Marketing Surveillance
- Sub-Programme 5: Complementary and Alternative Medicines (CMs)
- Sub-Programme 6: Veterinary Medicines
- Sub-Programme 7: Laboratory Services

Objectives

90% of clinical trial applications evaluated within an evaluation cycle

80% of applications for the sale of an unregistered health product evaluated within a specified timeline

60% of medicines with public health priority evaluated with regulatory decision every quarter

Reports of new adverse events and signals that have been assessed, actioned and concluded are published quarterly

An inclusive vigilance framework for all health products developed for approval

Programme Five: Medical devices, diagnostics and radiation control

Purpose

The main purpose of the Programme is to develop and maintain regulatory oversight of medical devices, ionizing and non-ionizing radiation emitting devices, and radioactive nuclides. Core functions for this programme include:

- Licensing of medical device establishments;
- Registration of medical devices and radiation emitting devices and radioactive nuclides;
- Designation and supervision of conformity assessment bodies;
- Conducting inspections of medical device establishments;
- Post-marketing surveillance and vigilance; and
- Approval of clinical trials

Medical Devices and Radiation Control currently exist within Programme 5 of this transition phase of SAHPRA's operational structure. It is being reconsidered for inclusion in the other programmes as all of the functions can be met in Programme 2, 3 and 4. This re-engineering proposal is underway and will be submitted by the Board in the adjustments budget in September 2018 to help streamline and reposition the programmes.

There are two sub-programmes, namely:

- Sub-programme 1: – Medical Devices
- Sub-programme 2: – Radiation Control

Objectives

40% of medical device establishment licence applications finalised within defined timelines

20% of Regulatory decisions taken on Medical Device applications within pre-defined timeline

70% of licence applications for facilities and radiation sources finalised within defined timelines

40% of licenses issued for non-ionizing radiation emitting devices and radioactive nucleides

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Details of Medium Term Expenditure Framework (MTEF) budget

SUMMARY OF ECONOMIC CLASSIFICATION OF PAYMENTS	2018/19	2019/20	2020/21	2021/22
	Actual	Budget Estimates	Budget Estimates	Budget Estimates
REVENUE	**240,335,485**	**308,274,000**	**303,028,000**	**303,624,000**
- Fees	72,059,772	112,000,000	132,500,000	145,000,000
- Interest received	4,907,134	3,000,000	3,000,000	3,000,000
- Backlog reduction project		10,000,000	-	
- Goods and services in-kind from NDOH	38,179,579			
- Treasury allocation	125,189,000	183,274,000	167,528,000	155,624,000
TOTAL CURRENT PAYMENTS	209,163,253	308,274,000	303,028,000	303,624,000
Compensation of employees	119,066,656	137,610,553	151,949,371	163,697,164
Goods and services	51,917,018	165,985,547	147,899,787	133,121,836
Goods and services in kind from NDOH	38,179,579			
TOTAL PAYMENTS FOR CAPITAL ASSETS		4,677,900	3,178,842	6,805,000
TOTAL PAYMENTS	209,163,253	308,274,000	303,028,000	303,624,000
Surplus / Deficit	**31,172,232**	**-**	**-**	**-**

Key considerations of the budget

- The SAHPRA Baseline increased from R125.1 million (2018/19) to R183.2 million (2018/19)
- Increase is a result of the remaining 50% transfer of Radiation Control budget allocated to SAHPRA
- Treasury funding of the backlog project (R40 million in Y1 and R20million in Y2)
- Baseline for 2020/21 – R167.5 million and 2021/22 – R155.6million
- SAHPRA will be able to retain its revenue use it for its operations
- New fees to be published for public comment in 2019-20
- Fees to be charged for services previously not charged for, e.g. medical devices, radiation Control
- Call-up notice for Complementary Medicines establishments to be licenced

Budget allocation per programme

Strategic Allocation per Programme	Medium term estimates (SAHPRA)		
	2019/20	2020/21	2021/22
1) Administration	81,076,000	94,778,000	104,454,000
2) Authorisation Management	68,663,000	44,162,000	25,297,000
3) Inspectorate And Regulatory Compliance	56,209,000	57,711,000	60,603,000
4) Medicines Evaluation and Registration	65,440,000	67,585,000	71,449,000
5) Devices and Radiation Control	36,886,000	38,792,000	41,821,000
	308,274,000	**303,028,000**	**303,624,000**

Backlog Budget

BACKLOG	2018/19	2019/20	2020/21	2021/22	TOTAL
REVENUE					
Treasury Allocation		10 000 000	20 000 000		**30 000 000**
Treasury Allocation		30 000 000			**30 000 000**
Sahpra Revenue from fees	35 000 000				**35 000 000**
Centers for Disease Control and Prevention (CDC) - Donor funding		24 000 000	0	0	**24 000 000**
Bill and Melinda Gates Foundation - Donor funding		12 500 000	25 000 000	12 500 000	**50 000 000**
Clinton Health Access Initiative (CHAI) - Donor funding	1 400 000				**1 400 000**
					-
TOTAL REVENUE	**36 400 000**	**76 500 000**	**45 000 000**	**12 500 000**	**170 400 000**
EXPENDITURE	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Compensation of employees		7 066 667	10 600 000	7 066 667	**24 733 333**
External Evaluators (Domestic)		16 950 000	33 900 000	16 950 000	**67 800 000**
External Evaluators (International)		46 125 000	92 250 000	46 125 000	**184 500 000**
Goods & Services		6 075 000	12 150 000	6 075 000	**24 300 000**
Digital/IT		1 025 000	2 050 000	1 025 000	**4 100 000**
Total Expenditure	**-**	**77 241 667**	**150 950 000**	**77 241 667**	**305 433 333**
Surplus/shortfall	**36 400 000**	**- 741 667**	**- 105 950 000**	**- 64 741 667**	**- 135 033 333**


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