

# Thank you for joining us today



Prof. Helen Rees, OBE  
Chairperson



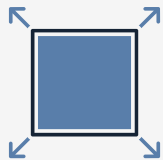
Ms. Portia Nkambule  
Acting CEO



Mr. Davis Mahlatji  
Head, Backlog  
Clearance Taskforce



The South African Health Products Regulatory Authority (SAHPRA) was launched in February 2018, replacing the Medicines Control Council (MCC)



SAHPRA became a Schedule 3A independent public entity, with an expanded scope:

- Medicines
- Scheduled substances
- Clinical trials
- Medical devices
- In-vitro diagnostic devices
- Radiation control

## SAHPRA's 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* ”

# SAHPRA faced multiple challenges upon launch



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



SAHPRA's largest challenge was an inherited backlog of medical products applications, defined as:

“ All applications<sup>1</sup> submitted which are yet to receive final approval (including certification), as of 31 January 2018<sup>2</sup>

# Top facts about the inherited backlog

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

**1992**

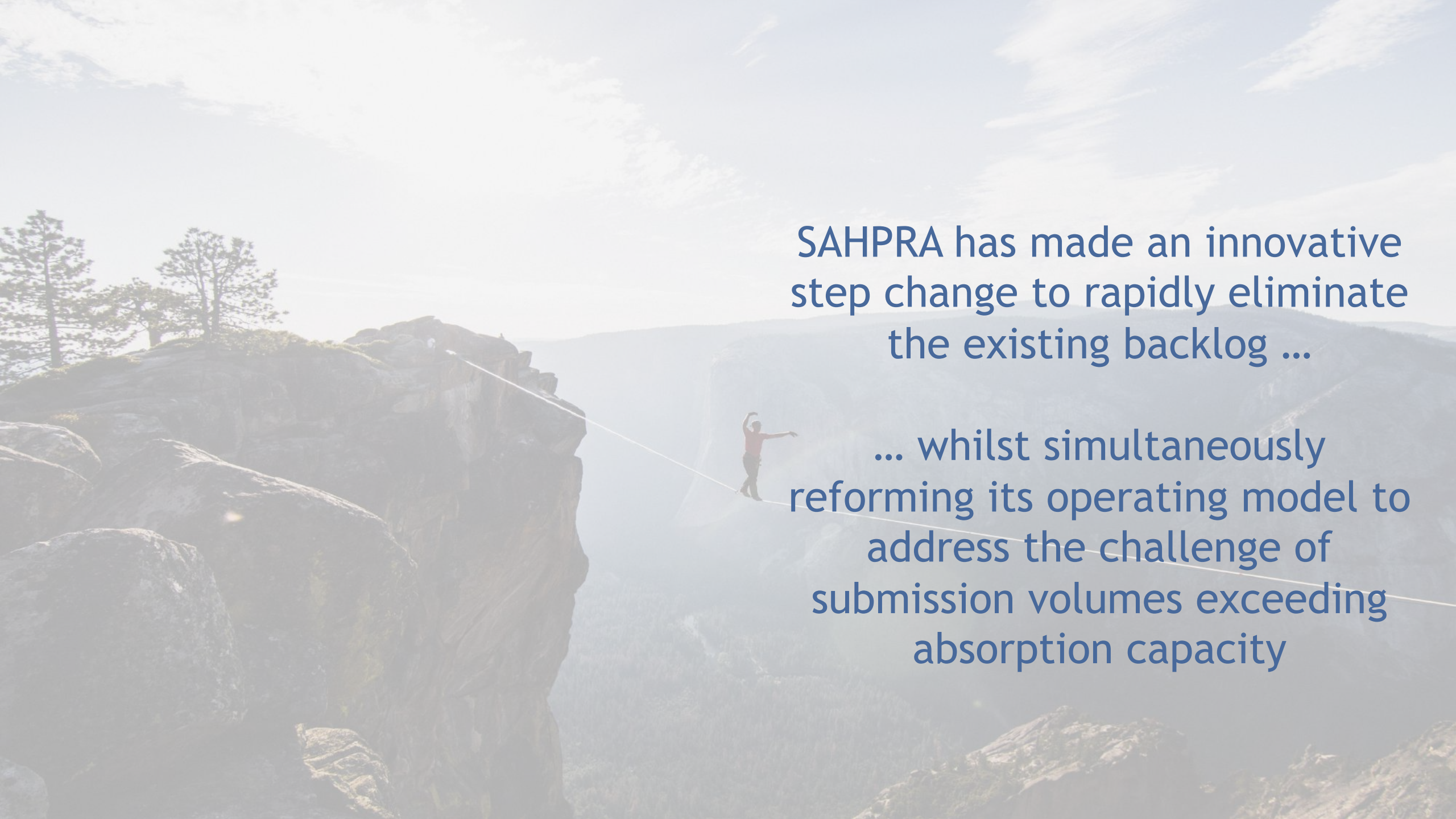
Submission year  
of the oldest  
backlog  
application

**50%**

New registration  
backlog  
applications older  
than 5 years  
(2013)



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

A person is walking a tightrope across a deep canyon. The tightrope is stretched between two rocky outcrops. The person is in the middle of the canyon, balancing on the rope. The background shows a vast, hazy landscape with mountains and a forested valley. The sky is bright and cloudy.

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

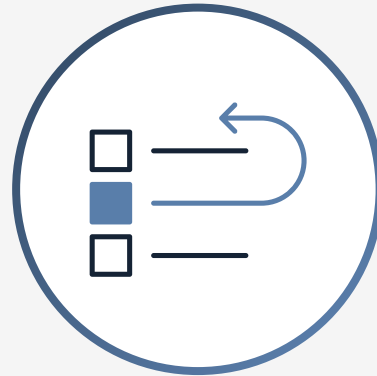
The ambition of the SAHPRA Board:  
To clear the backlog within 2 years



# Three pillars of SAHPRA's backlog clearance strategy



Reduce the number of applications that require evaluation



Segment and prioritise remaining applications

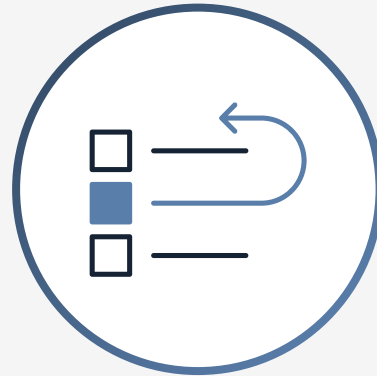


Design and implement new models for evaluation

# Pillar 1



Reduce the number of applications that require evaluation



Segment and prioritise remaining applications



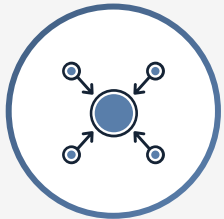
Design and implement new models for evaluation



# 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

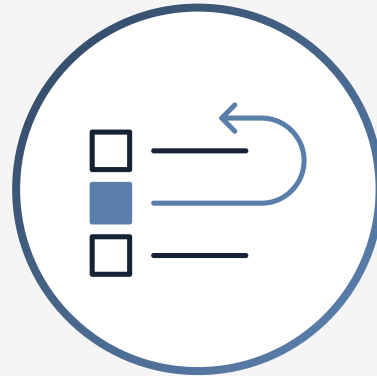


As a result of Pillar 1, ~3,000 new registration applications have been withdrawn and R35M in unpaid application fees were collected

# 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<sup>1</sup>

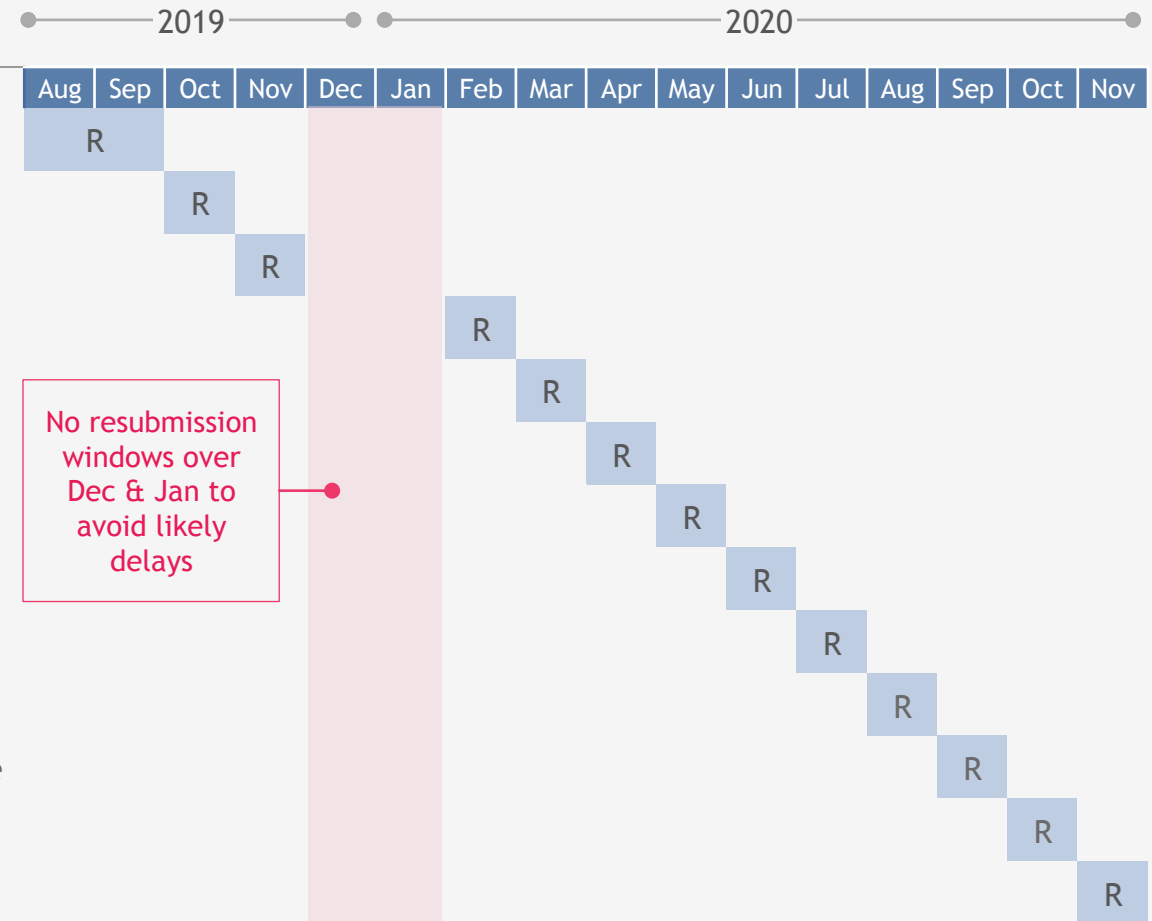
1. All APIs that do not fit into a designated therapeutic area, including anti-histamines and other allergy medications  
Source: Application survey database, Engagement with NDoH



# 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<sup>1</sup>



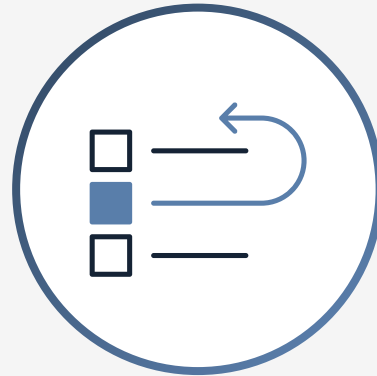
■ Resubmission window ■ Festive season

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

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)

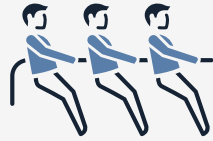


World Health Organisation (WHO) Prequalification

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



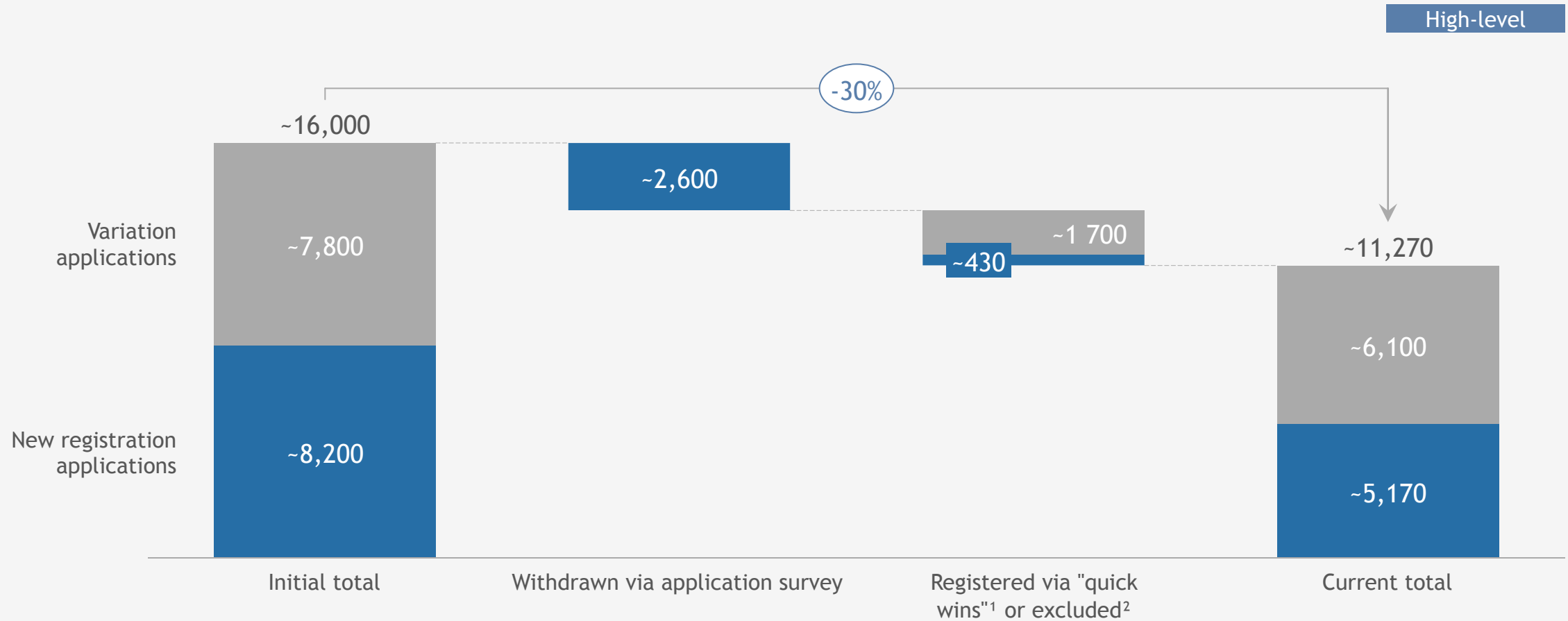
### Effective program management

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

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



## 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

# 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



**SAHPRA**

SOUTH AFRICAN  
HEALTH PRODUCTS  
REGULATORY AUTHORITY