SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

Update on SAHPRA

SAPRAA Meeting – Professor Helen Rees, Chairperson of the SAHPRA Board

12 APRIL 2019

Objectives for today's presentation

Provide an update on SAHPRA

Provide an update on the Backlog Clearance Program

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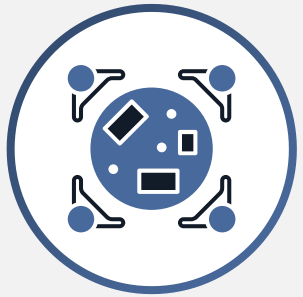
The South African Health Products Regulatory Authority (SAHPRA) was launched in February 2018 as a Schedule 3A independent public entity

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”

Despite challenges, SAHPRA is establishing an efficient, effective, sustainable regulator



Finalised Section 197 transfer of staff

Progressing appointment of new Executive: CFO, IT Director and Company Secretary have joined; ongoing CEO recruitment focus

Moved into new (emergency) physical premises at CSIR and established required phone / internet connectivity

Dramatically re-engineered & automated Section 21 processes

Developing a new fees & performance metrics model

Please note SAHPRA has new email addresses

General enquiries:
enquiries@sahpra.org.za

Emergencies:
emergency@sahpra.org.za

Backlog Clearance Team:
backlog@sahpra.org.za

Objectives for today's presentation

Provide an update on SAHPRA overall

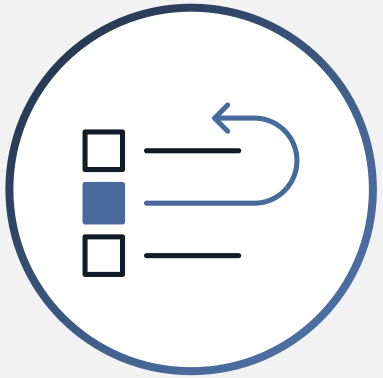
Provide an update on the Backlog Clearance Program

Recap: Top facts about SAHPRA's inherited backlog

1. SAHPRA’s backlog comprises ~16,000 applications: 8,300 new registration and 7,200 variations
2. SAHPRA’s backlog dates back to 1992
3. 50% of the new registrations backlog is ≥5 years old (submitted 2013 or earlier)
4. 16 applicants account for 50% of the new registrations backlog
5. Generics comprise >90% of the new registrations backlog
6. 15 molecules comprise 16% of the new registrations backlog, each averaging 20 applicants — which provides a batch processing opportunity
7. There are 3,400 variations amendments awaiting certification

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

Part of SAHPRA's vision, written into the founding legislation, is to capture the benefits of reliance

SAHPRA will recognise a regulatory authority that:

- *Was a member of ICH prior to 23 October 2015: US FDA; EMA, Japan MHLW*
- *Was an ICH observer prior to 23 October 2015: Swissmedic; Health Canada*
- *SAHPRA has had significant previous engagement: Australia TGA; United Kingdom MHRA; Zazibona; WHO PQ*

Note: FDA = Food and Drug Administration; EMA = European Medicines Agency; MHLW = Ministry of Health, Labour and Welfare
Source: WHO/PQT Guidance Document 15 February 2017

The decisions of these recognised regulators will translate to new evaluation 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

Recognition

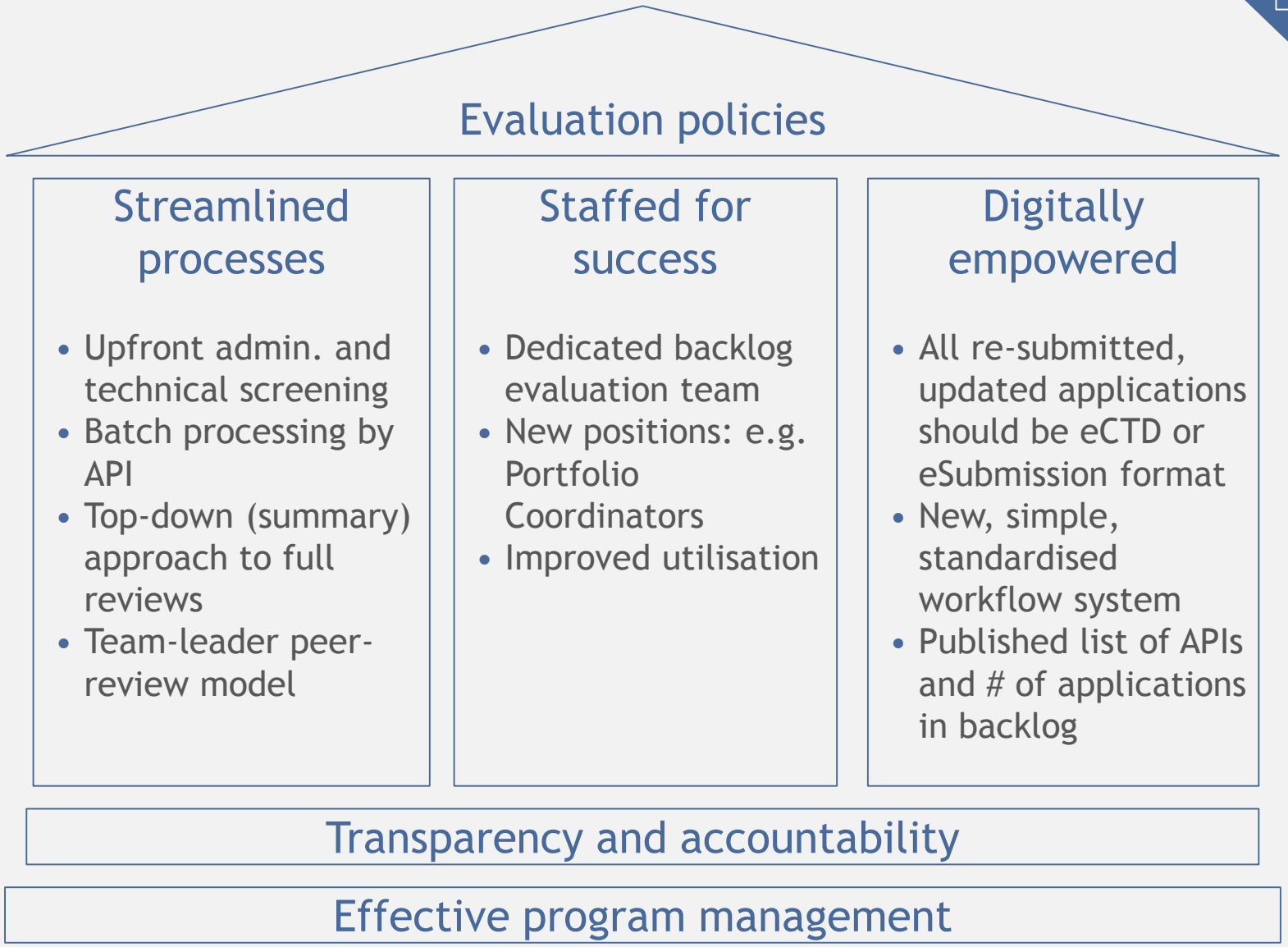
Accept reference authorisation without review

Notification

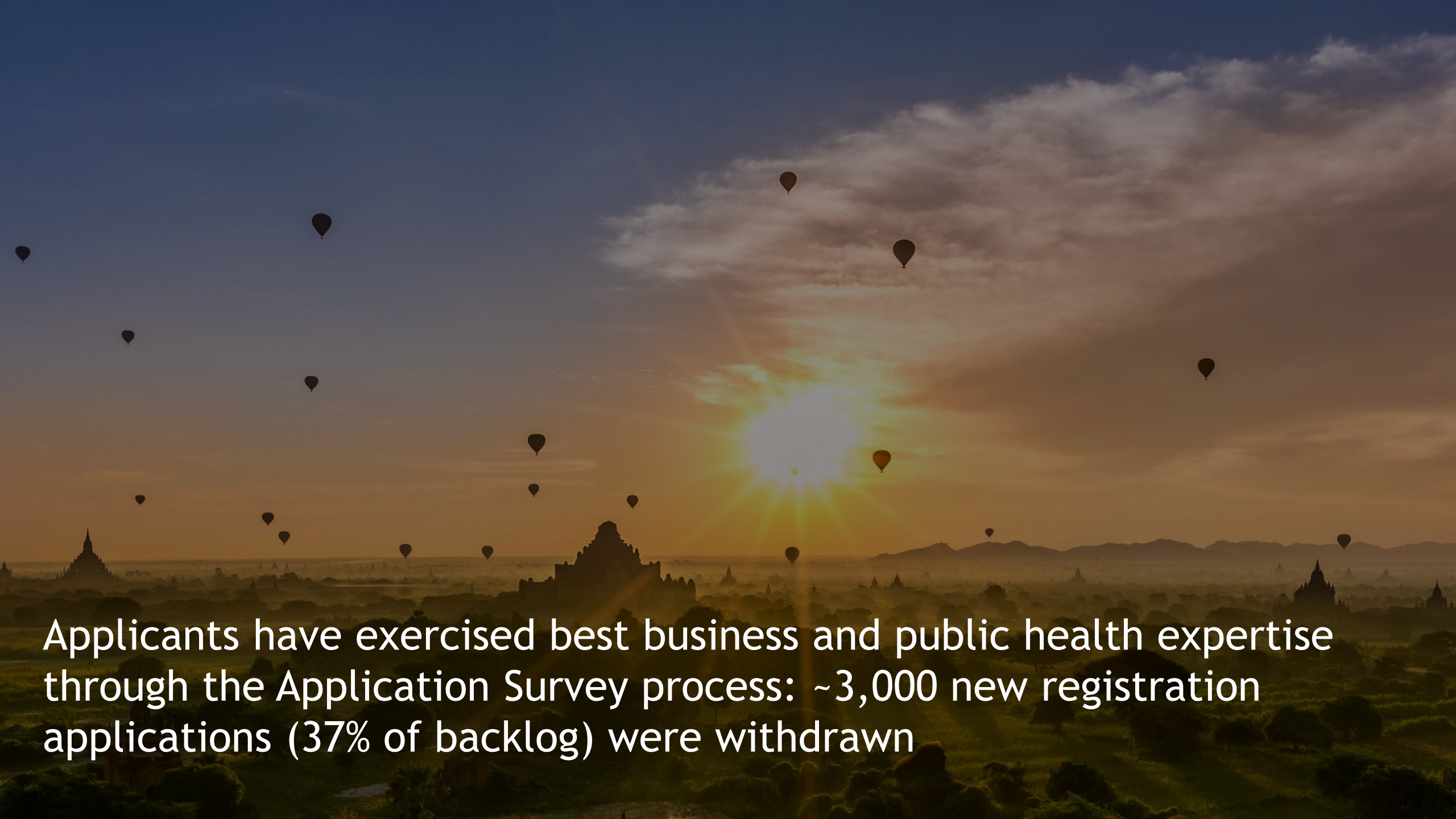
Applicant can "do then tell"

Extent of evaluation by SAHPRA

In addition to new policies, a new operating model is required




We have made significant progress in preparing to launch SAHPRA's Backlog Clearance Program



Applicants have exercised best business and public health expertise through the Application Survey process: ~3,000 new registration applications (37% of backlog) were withdrawn

SAHPRA is also delivering 'quick wins'

Variation certificates:
320 certificates signed by Acting CEO

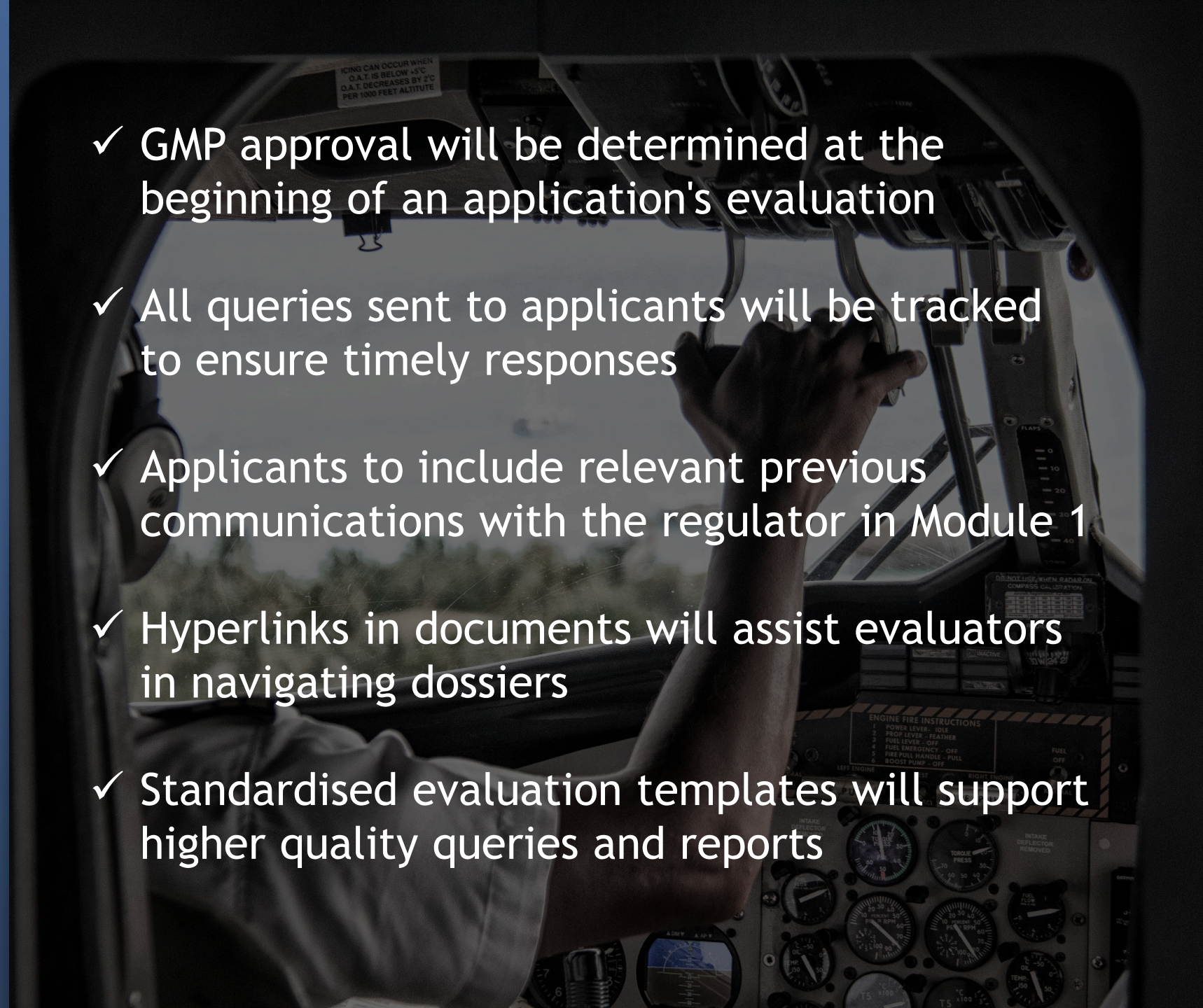
Project Starburst:
480 applications submitted; 257 'eligible';
29 applications registered (so far)

Work continues on two important enablers…

Staffing: Recruitment for dedicated personnel will begin in next 4-6 weeks

Digital: Customisation, testing and installation of solutions underway

…and we have continued to streamline processes through learnings from our pilots



- ✓ GMP approval will be determined at the beginning of an application's evaluation
- ✓ All queries sent to applicants will be tracked to ensure timely responses
- ✓ Applicants to include relevant previous communications with the regulator in Module 1
- ✓ Hyperlinks in documents will assist evaluators in navigating dossiers
- ✓ Standardised evaluation templates will support higher quality queries and reports


With reliance, it is easy to see where we are and where we want to be, but getting there is difficult

Key lessons learned thus far

Be prepared to have challenging conversations: designing new evaluation procedures requires debating about many different scenarios and choices

Examining the regulator's risk appetite requires engagement and time of senior leadership

Incorporating reliance is as much a mindset step-change as it is an update to evaluation procedures: staff need to be brought along on the journey

Industry engagement, if well structured, is a source of strength, not conflict: SAHPRA has monthly engagement with two industry working groups

Ask for help from international regulatory colleagues and partners: SAHPRA is very thankful for the support received from a variety of regulators and international partners

Good news: Re-engineered processes are all more efficient than SAHPRA's 'old' processes

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

6 guiding principles for harmonisation with BAU

All processes from the Backlog Clearance Program will be adopted for BAU by default unless a clear business case (based on volume and quality) is made

SAHPRA will be bold: policies and processes will leapfrog to reflect the practices of leading regulatory authorities

Safety, efficacy and quality of medicines registered in South Africa will reflect global best practice

Administrative justice will be delivered: similar applications will receive fair, comparable treatment

Communication is key: regular, transparent dialogue with internal and external stakeholders

Outputs and other key performance indicators will be rigorously tracked and used to inform operational priorities, people management and ongoing organisational improvement

Draft milestones to 'go live'

Today: Key guidelines published for 30 days comment

16 April: Variations workshop with industry

May: Recruitment of Backlog Clearance Team begins

Beginning June: Final documents published

Mid June: New registration and Type II variation resubmission windows published

August: First backlog resubmission window opens

Given the complexities of such a large change program, we will be need to be dynamic and flexible in our approach


We look forward to the journey ahead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