SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

SAHPRA UPDATE

SAAPI, Conference 17 May 2019, CSIR ICC

Davis Mahlatji

Outline

Amendment to the Regulations

Update on Backlog Clearance Program

Refinement of reliance Policies

GMP inspections

Medicine registration process

Complementary Medicines

Amendment to the Regulations

Regulations

Regulation 11

Exemption from single exit price for medical devices

Fees

Inflation adjusted fees (with few additional fees - GCP Inspection and Amendments)

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Update on Backlog Clearance Program

Application Survey and resubmission windows

Publication of comprehensive list applications in backlog

-validation of applications that will evaluated in the backlog
-confirmation of withdrawal from backlog

To resolve Transfer of Applicancy

-we will be contacting applicants directly to obtain proof of these transfers
-ensure that we communicate with the applicant who has legal authority over an application

Resubmission Windows

Will be published in the next month, to enable you to start preparing your applications
For each resubmission window, we will include:
•Preliminary timeframe (i.e. when and how long the window will be)
•Therapeutic areas included in each window, defined by a list of APIs
•Types of medicines included in each window (e.g. NCEs or Generics)

Transfer Applicancy

There is significant number applications that are subject to transfers of applicancy,

SAHPRA will only recognise finalised transfers of applicancy where legal ownership/responsibility of the application has been transferred-
To allow SAHPRA to communicate with the updated applicant.

SAHPRA has issued a Variations Addendum for public comment

The Variations Addendum outlines 21 exceptions to the EU variations classification guideline across Clinical, P&A, N&S, and Veterinary, which potentially affect up to 3 areas:

- Identification codes
- Evaluation procedures
- Required documentation

There are 4 types of exceptions affecting the 3 areas

- Exclusions: Codes, procedures and, documentation that will not be adopted
- Additions: Additional codes, procedures and, documentation created by SAHPRA, not covered explicitly in the EU variation classification guideline
- Alterations: EU codes, procedures and, documentation adopted and adapted by SAHPRA, with a different procedural treatment
- Clarifications: EU codes requiring further clarification to facilitate adoption

Following public comment, SAHPRA will have two weeks to synthesise comments, agree internally on changes to adopt and publish the final version

Variations Addendum has been included in the guidelines document you have received

SAHPRA requires a digital variations portal that meets 3 criteria to facilitate Type I variation applications

Functional capabilities

Design must meet the key functional requirements to deliver re-engineered variations process

Development duration

Be ready for launch within a short to enable 'quick wins' for Type I variation applications in the inherited backlog

Implementation cost

Cost effective solution

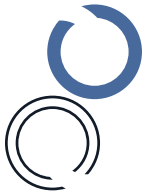
Functional capabilities will be delivered through key features for Variation portal

Enables the digital submission of variation applications along with any supporting documentation

Provides approval workflows for both the applicant (to enable higher quality submissions) and for SAHPRA

Populates a centralised database of variation applications with details about applicant, variations applied for and procedures necessary for evaluation

Provides Port Health with read-only access to centralised database to allay security concerns

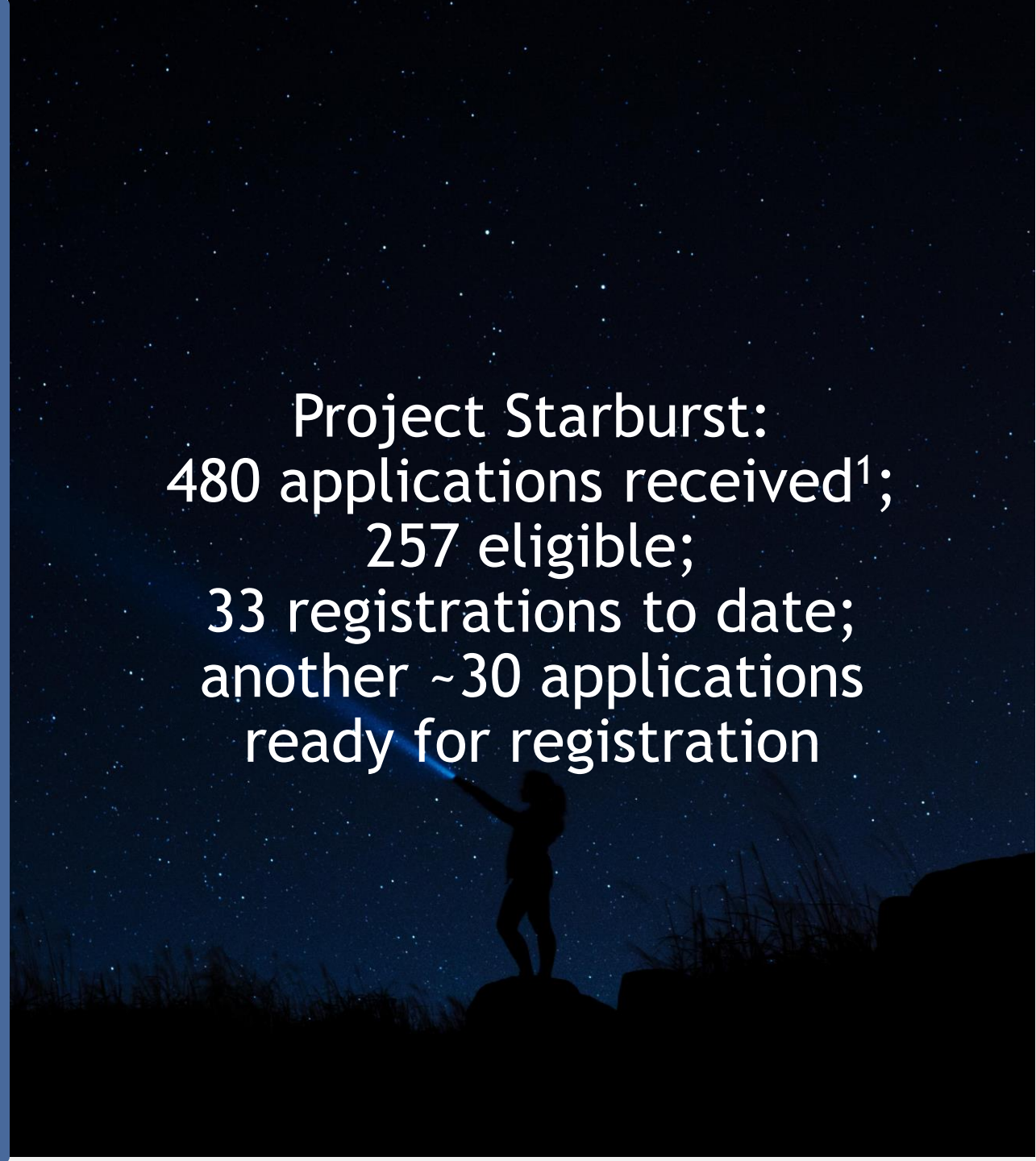


Integrates with eCTD and eSubmission digital solution (target state)

Quick wins are accelerating

Variation certificates:
~600 certificates signed / ready to be signed by Acting CEO

Project Starburst:
480 applications received[1];
257 eligible;
33 registrations to date;
another ~30 applications ready for registration



1. Including every strength, dosage form, duplicate

key other priorities for SAHPRA before ‘go-live’ on the Backlog Clearance Program on 1 August

Pilot

- SAHPRA has already captured multiple key learnings from the Pilot
- Going Forward; We will finalise the remaining in-process evaluations of pilot applications
-

Re-evaluate efficiencies in PI evaluation

- prioritise molecules

Guidelines

- Finalisation of tranche 1 and 2 documents shared with industry

Digital solution

Online Portal for Type 1 and Type 1B variations. eSubmission and workflow management

Project Starburst

- Complete all legible applications end of May 2019.

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Refinement of Reliance Policy

EMA-Central Procedures (CP) and Decentralised procedure (DCP)
-inclusion of DCP will

WHO PQ and ZAZIBONA
-SAHPRA will invite expression of interests (EOI) for WHO PQ and ZAZIBONA pathways in the next few days or week

To maximise potential for reliance, SAHPRA needs to expand beyond CP as its eligibility is restrictive

Assessment of applications should be RISK based

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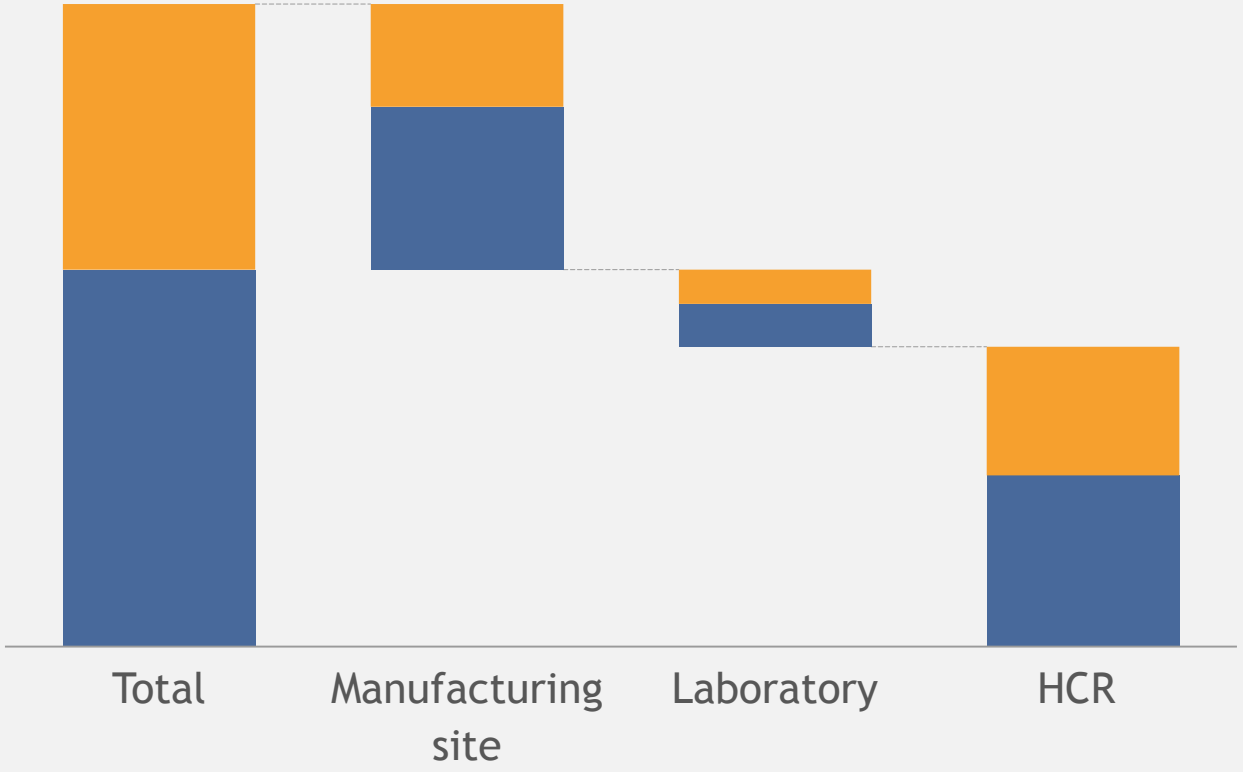
GMP Inspections
Following the survey and indicated that significant number of sites may be overdue



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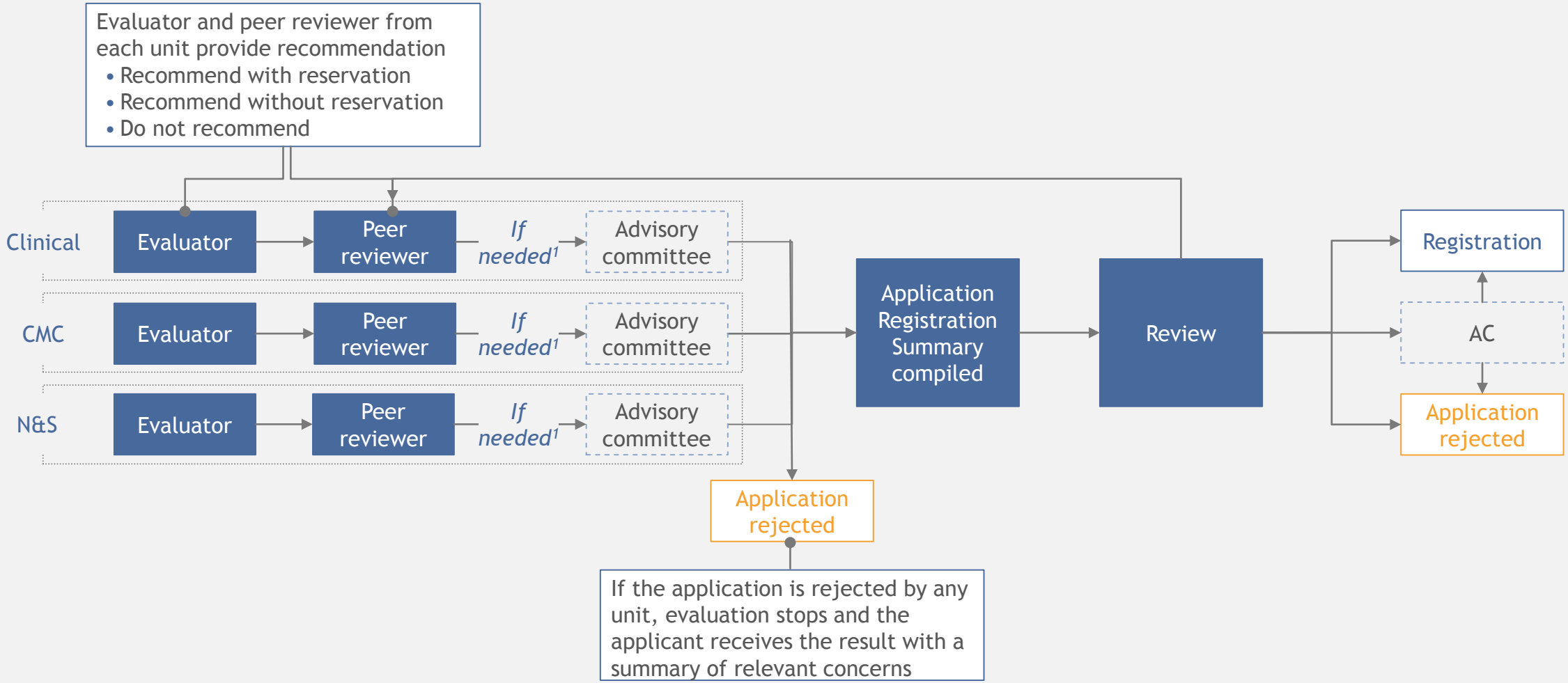
Overview of new medicines registration process



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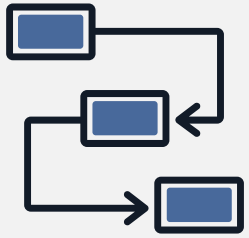
Complementary Medicines…

The Unit is working on a regulatory system that seeks to revise the current approach complementary medicine

This will include consultation with stakeholders, with SAHPRA staff, CMC representatives and individual associations, in order for the SAHPRA to present the amended approach and to discuss any areas of concern. The consultations dates shall be announced by the SAHPRA upon the revised approached finalised

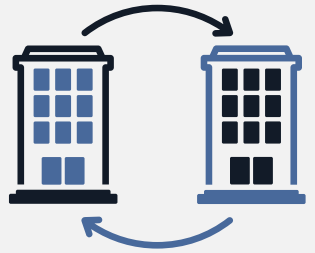
SAHPRA Immediate Future Activities



Streamlined processes

Digitally enabled

Staffing for success



Stakeholder engagement

Important Deadlines

01 June	Deadline for industry comments on eDocuments guidelines and templates
10 June	Deadline for industry comments on Variation Addendum documents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