



SAHPRA Information Technology - Digital Transformation

SAHPRA ICT Strategic Principles and Drivers

- SAHPRA's IT team is committed to the development of responsive and innovative IT services that meet SAHPRA's needs and enhances the end-user experience



Strategic Drivers



Driver 1 – Meet Industry and Stakeholder Expectations



Driver 2 –Digitally Transform and Automate Business Processes

Strategic Drivers



Driver 3 – Establishment of Reliable Enterprise IT Infrastructure



Driver 4 - Enhance Data and Information Security

Strategic Drivers



Driver 5 – Deliver value through proper Corporate Governance of ICT

Driver 2 – Digital Transformation

| Actions Underway/Completed | Future Actions |
|---|--|
| Identify the Core Business Process to be digitalised | Development/Procurement of an Integrated Regulatory Information Management Systems (R-IMS) |
| Business Process Mapping | Phased implementation of R-IMS |
| Define and document business and user requirements | |
| Develop a rollout plan for digital transformation | |
| Implement strategic short-term interventions to accelerate digitalization | |
| Monitor and measure impact of digital interventions | |

Digital Transformation Challenges

 Digital Execution Maturity of the organization

 Adequate funding support for Digital Tools and Change Management process

 Competing Priorities

 Deploying Integrated and Interoperable systems that will support seamless operational processing

Activities for remainder of FY2022/2023

1. Deployment of consolidated stakeholder engagement portal

Query/Complaint handling platform

Application/submission management platform

Reporting/Tracking platform

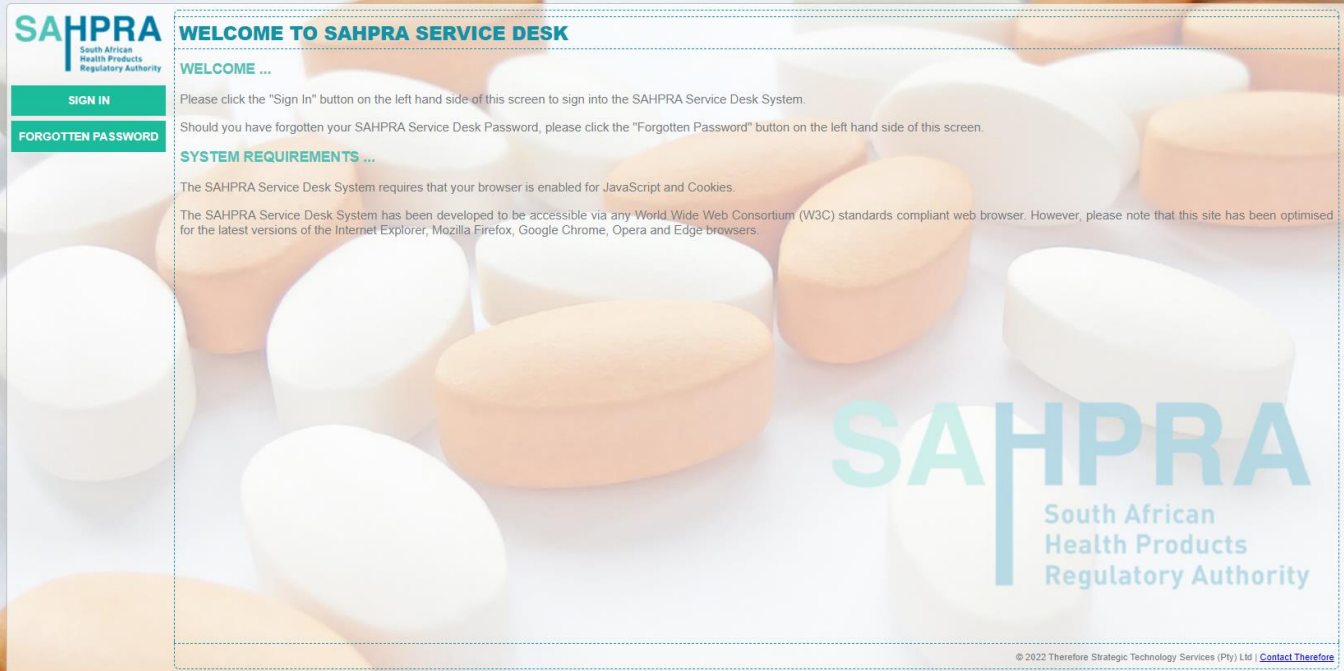
Dashboard/reporting platform

Single contact point with the organisation through the Quantum™ portal....

2. Procurement of a Regulatory information and document management solution – integrated with stakeholder portal and initiation of phased roll-out

3. Deployment of Quality Management software, eLearning tool, Risk management and Audit/Inspections tool

SAHPRA Service Portal



SAHPRA
South African
Health Products
Regulatory Authority

WELCOME TO SAHPRA SERVICE DESK

WELCOME ...

Please click the "Sign In" button on the left hand side of this screen to sign into the SAHPRA Service Desk System.

Should you have forgotten your SAHPRA Service Desk Password, please click the "Forgotten Password" button on the left hand side of this screen.

SYSTEM REQUIREMENTS ...

The SAHPRA Service Desk System requires that your browser is enabled for JavaScript and Cookies.

The SAHPRA Service Desk System has been developed to be accessible via any World Wide Web Consortium (W3C) standards compliant web browser. However, please note that this site has been optimised for the latest versions of the Internet Explorer, Mozilla Firefox, Google Chrome, Opera and Edge browsers.

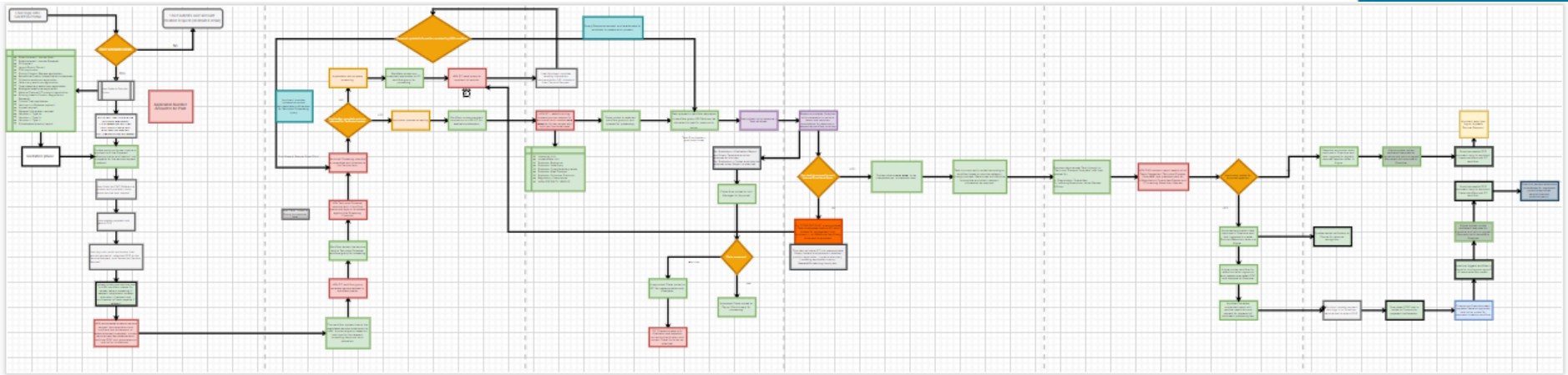
SAHPRA
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Health Products
Regulatory Authority

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Typical Service Task Requests

- Establishment License New
- Establishment License Renewal
- S21 permit
- Import/Export Permit
- S36 Application
- Priority Product Review application
- Borderline Product classification submission
- Orthodox medicine registration
- Veterinary medicine registration
- Complimentary medicines registration
- Biological medicine registration
- Medical Device/IVD product registration
- Existing Health Product Registration Renewal
- Clinical Trial application
- Vaccine Lot Release request
- Appeal request
- General Information request
- Variation - Type Ia
- Variation - Type Ib
- Variation - Type II
- Substandard product report

Business Process Management Flow



Business Process Management Flow



Users select tasks -> complete application form -> system prompted per task type -> fee calculation per service selected -> allows attachment of respective application forms, supporting documents and POP (Payment Gateways – process being investigated)



Tasks routed through workflow process to various functional areas for processing -> service objectives linked to different steps to allow for processing time tracking through management reports

Business Process Management Flow

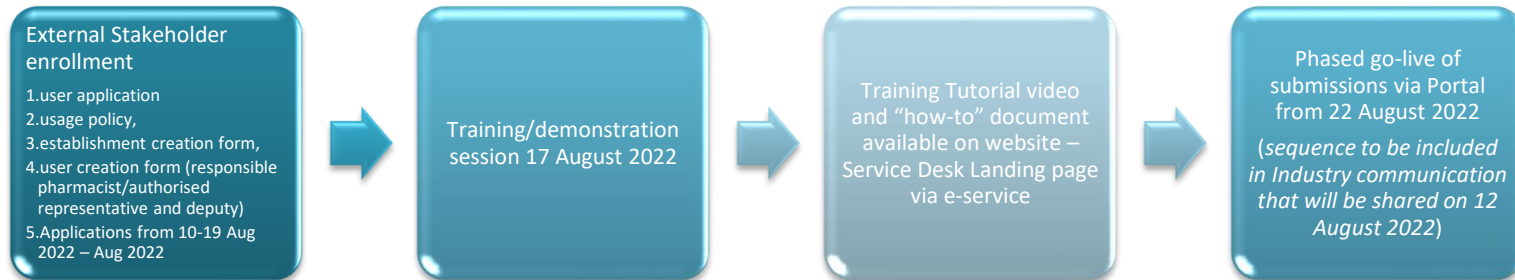


Integrated with Document-Case Management-Evaluations Software tool
-> APIs manage flow of submitted meta data and documentation in
prescribed format/structures



Improved operational coordination and central case history for greater
process efficiency

Business Process Management Flow – Phase I



The Journey!



THANK YOU