

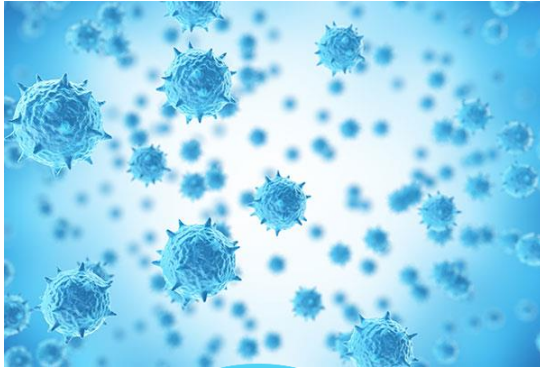


Business Continuity Plan in response to COVID 19 pandemic

Date: 20 March 2020

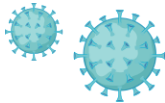
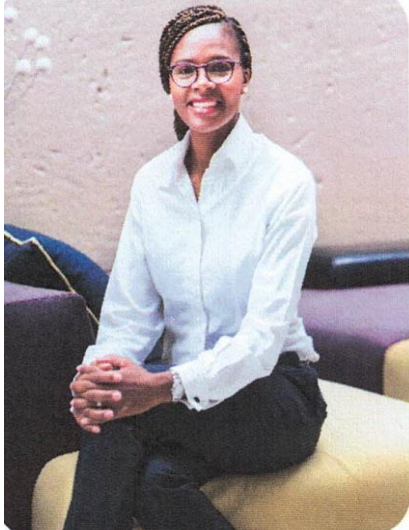


Introduction and Background to COVID 19



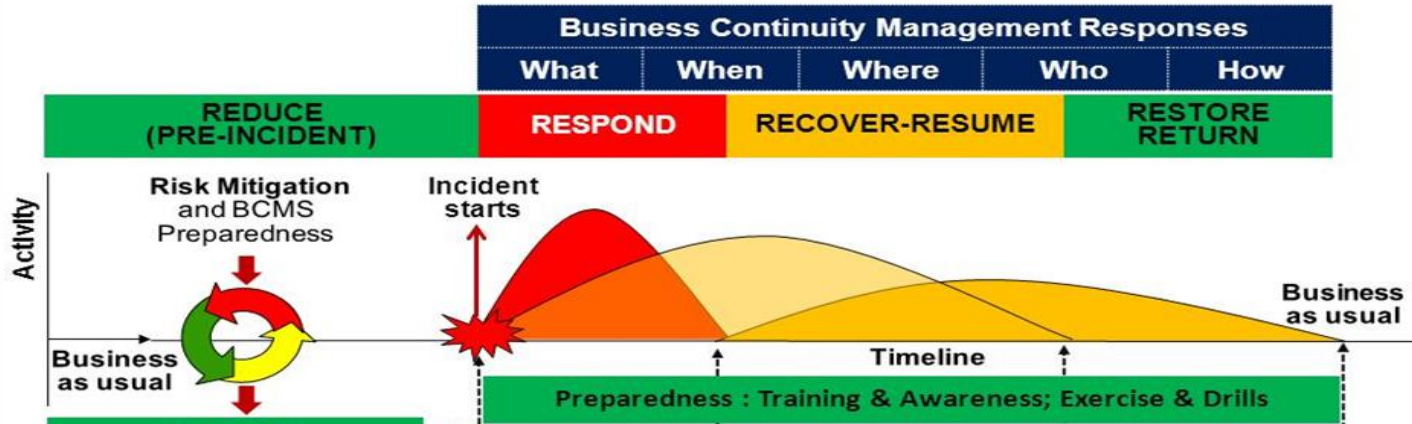
- The COVID-19, also known as the Coronavirus, outbreak has become a major concern for individuals and businesses as the virus continues to spread globally with an accelerating and unpredictable speed.
- Indications are that the threat will likely increase.
- On Friday, 20th March 2020, 150 confirmed number of cases of Coronavirus in South Africa registered on the NDOH sa cornoavirus portal.

Introduction to COVID 19 Cont..



- The SAHPRA Executive Management takes the responsibilities of its staff and its corporate responsibility to all stakeholders seriously.
- SAHPRA Management Team has set up a COVID -19 Containment Task Team on the 17th of March 2020 to ensure adequate response, to safeguard staff and meeting its public health mandate in the health space at a crucial time.
- The team has thus far profiled the risk of business disruption due to pandemic outbreak the Coronavirus (COVID 19).
- Further, the team has analysed the impact it might have on operations of the organisation and formulated Business Continuity Plan to mitigate this risk.

Risks Name: Business Disruption(COVID 19)



Risk Description:

SAHPRA may be unable to timeously respond to business disruption that could be caused by wide spread of diseases (i.e. COVID 19) and other un-identified continuity threats resulting in management failure to deliver critical entity services to its stakeholders efficiently.

EG. Respond to shortage of medicines resulting from limited supply of imported APIs, disruption in services that prevent access to health care products for public health priority.

Potential Disruption Scenarios

The following are two (2) potential scenarios that are most likely materialize

Scenarios	Detailed definition	Impact on SAHPRA human resource	Impact on SAHPRA business (Processes, Property, Equipment's, Information systems, 3 rd Parties)
Scenario1 Business Disruption- COVID 19 (Short Terms = 1Month)	Staff off work due to illness or care giver demands for a short period of time.	<ul style="list-style-type: none">• Loss of critical staff due illness, need for self quarantine• Loss of critical staff due to care giver demands with schools and child care facilities being closed.• Activation of staff contingency plan for critical services• Activation of expedited process for medicines registration, variation and section 21/drug shortage	<ul style="list-style-type: none">• Disruption of critical service or processes along SAHPRA's business• Disruption of information systems due to loss of support services from external parties• Inability to access critical external facilities and equipment's(Laboratory/Evaluations/Inspections)• Shortage or Disruption of supply chain service(stationery/cleaning services/security services/equipment's/cancellation of business travels)

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Scenario 2 Business Disruption- COVID 19 (Long Term = More than 1Month)	Positive case/s reported for SAHPRA or on the CSIR campus, resulting in a complete shut down of the SAHPRA offices	<ul style="list-style-type: none">• Activation of remote work activities (i.e. All staff work from home)• Closure of front line offices (i.e. manual applications)• Extended IT support services for employees requires remote access to systems• Activation of staff contingency plan for all critical services	<ul style="list-style-type: none">• Inability to access property or building due to contamination• Disruption of information systems due to loss of support services from external parties• Inability to access critical external facilities and equipment's (Laboratory/Evaluations/Inspections)• Shortage or Disruption of supply chain and contractor services (stationery/cleaning services/security services/equipment's/cancellation of business travels)

Risks Name: Business Disruption(COVID 19)

Current Controls



- Emergency and Epidemic disease response plan (Business Continuity Plan)
- COVID -19 containment task team monitoring continuity treats and implementation of mitigations.
- Adoption of National Directives(NDOH workplace containment guideline and National Health Directives.
- SAHPRA Social distancing guideline communicated to all employees.
- Activation of Priority Application Process Guidance for New Medicine Registration, Variations and Section 21 /Drug Shortage.

Critical activities/processes per program

Program 1: SAHPRA support functions

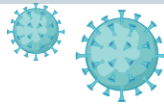
All support functions are critical

- Finance needs to be in the office as confidential information cannot leave site
- Human Resource function needs to be on site to provide ongoing support and monitoring of staff needs.
- IT has to be on site to ensure connectivity and provide on going support for remote working capabilities.
- The Office of the CEO and related functions will be on site to provide leadership and keep lines of communication open to stakeholders

Critical activities/processes per program

Program 2: Health Products Authorisation

- Document reception
- Uploading of New medicine, Responses & Variation applications
- Registration committee documents & meeting logistics
- New & amended certificates
- Document reception



Critical activities/processes per program

Program 3: Inspectorate and Licensing

Licensing

- Receive emailed license application, supporting documentation and POP.
- Conduct evaluation of the license application
- Populate the licence template
- Circulate the licence electronically to the Executives with recommendation
- Executive approval for the licence to be issued
- Licence is printed, signed by the CEO, scanned and emailed to the applicant.

Inspectorate

- Receive emailed supportive documentation, including Quality Management System
- Inspector conducts desktop/documentation inspection
- Inspector compiles the hours and sends the report to the external reviewer
- Inspector receives the reviewed report and sends to applicant with the amount charged
- Inspector waits for the applicant to respond with CAPAs
- Inspector evaluates the CAPAs, drafts a resolution recommending approval or rejection of the site.
- The resolution is emailed to the Executives for final approval.
- The resolution is printed, signed by the CEO and emailed to the applicant.

Critical activities/processes per program

Program 4: Clinical evaluation management	Program 4:Pharmaceutical evaluation management
<ul style="list-style-type: none">• Evaluation of new and amended clinical labeling;	<ul style="list-style-type: none">• Evaluation of Quality and Bioequivalence (Human and Veterinary)
<ul style="list-style-type: none">• Processing of new and amended clinical trial protocols; Progress reports; receiving and recording SAEs;• Receiving and capturing ICSRs;• Correspondence to Pharmacovigilance reporters;• Section 21 authorizations.	<ul style="list-style-type: none">• Evaluation of Biological Medicines (Q,S,E)• Variations (Quality and Bioequivalence) of registered medicines• Processing of Veterinary Clinical Trials• Processing Section 21 Human, Veterinary and Complementary Medicines• Post importation Testing Exemptions of Biologicals• Licensing of Complementary Medicines Facility

Critical activities/processes per program

Program 5: Medical devices and Radiation control

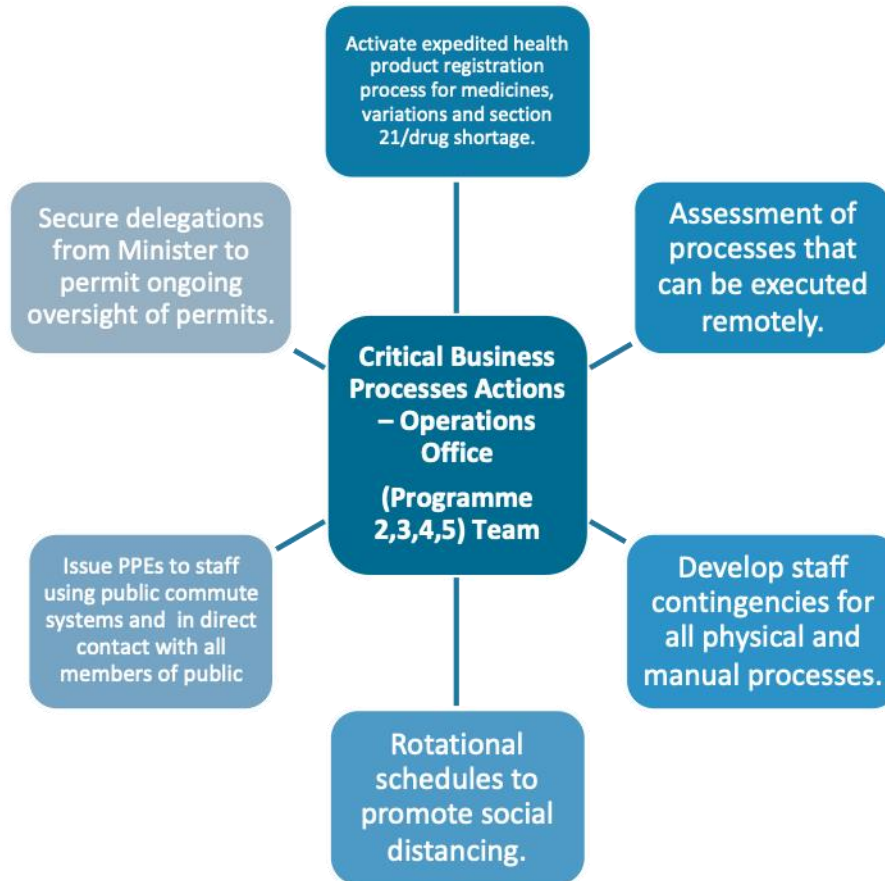
- Issuance of medical device establishment licenses
- Issuance of ionizing and non ionizing radiation licenses
- Management of incidents accidents involving ionizing radiation
- Access to database, servers, shared drives, printers and email system

Critical activities/processes per program

Backlog Clearance program

- Receiving of applications
- Uploading of applications for RW 5 and VW 1
- Validations of applications,
- Technical screening,
- Processing of registrations certificates,
- Monitoring evaluators performance.
- Monitoring end to end process.
- Access to the shared network folders and EursNext
- Receiving of applications

Mitigations Plans: Core Business Disruption(COVID 19)



Mitigations Plans: Business Disruption(COVID 19)

Critical requirements to execute role during long term disruption

Process step	Medicines	Medical Devices and IVDs	Section 21/Drug shortages
1	Access to shared drive (Medicines Shared Drive)	Access to shared drive (Medical Device Shared Drive)	Access to (Google suite, IT Expertise afterhours, contact number
2	5 Laptops and 3 Data cards	Remote peer review meetings	Data Card x 3 and Cell phone
3	3 Scanner and printer	Electronic Signature for Licences	Two resources/Employees
4	42 resources or employees	Scanner and printer	
5		Data Card x 3 and Cell phone	
6		Two resources/Employees	

Expedited health product registration process

Process step	Medicines Registrations (Ref Priority Application Guideline)
1	Basic information as per the submission guidelines 2.23 or 2.58 for the unique identifier
2	Motivation for COVID-19 use, Information on Name and Address of API source/s
3	Information on the Manufacturer, Packer, Laboratory of the final packaged product
4	cGMP certificates for the sites requested
5	Applicant will be given an application number and fees payable within five days, The applicant is required to submit five copies (on separate USBs) to be delivered at SAHPRA reception, CSIR Building 38
6	The applicant should email the signed proof of submission to santhani.chetty@sahpra.org.za
	Contact persons: Mrs Santhani Chetty and Mrs Silverani Padayachee (Contact details as per website)

Expedited health product licence process

Process step	Medical Devices and IVDs (Ref Priority Application Guideline)
1	Email new licence applications, amendments to existing licence applications and notifications of updated product list (NOTE: The notification process may not be used for Class C and Class D medical devices for COVID-19)
2	Applications will be screened and a letter of acknowledgment will be sent to the applicant (The acknowledgement letter may not be used in lieu of a valid SAHPRA licence)
3	The application will be reviewed, followed by a peer review process to ratify the decision to approve licence applications that meet the evaluation criteria.
4	An observation letter will be sent to the applicant in the event that a licence application does not meet the evaluation criteria. The deficiencies identified within the application will be documented in the observation letter.
5	The applicant is required to respond to the deficiencies noted in the observation letter within two working days.
6	Turnaround timelines are between 1 to 7 days
7	Contact Persons: Andrea Julsing and Jerry Molokwane (Contact Details as per Website)

Expedited health product registration process

Process step	Section 21/Drug shortages (Ref Priority Application Guideline)
1	Quick turn around with application received through Google suite
2	Telephone collaboration between two evaluators and senior managers to expedite approval
3	Monitoring of email sent to: Shortages @SAHPRA.org.za
4	Immediate update of application via email to an applicant.
5	Contact persons: Dr Munbodh and Tohlang Sehloho (Contact Details as per website)

Mitigations Plans: Business Disruption(COVID 19)

People or Human Resources – Human Capital Management Team

- Develop pandemic preparedness, response and continuity plans taking into account CSIR business continuity plan as the landlord.
- Set up and facilitate COVID -19 containment Task Team
- Monitor and implementation of COVID- 19 workplace containment guideline and national health directives. (NDOH Guideline) – implemented by HR, monitored by facilities manager to ensure compliance
- Monitoring of all ill/infected employees and regular testing of all suspected employees
- Monitoring sick leave for employees and output management for people working remotely
- Employees affected by schools closure - work remotely – output monitored
- Online staff communication and training - person symptomatic, what must I do in my corridor, in my building, on my campus.
- Restricted travel requirements

Critical requirements to execute role during long term disruption

- Manual approval of leave
- Leave policy to accommodate special circumstance
- Remote access to employees leave records
- Laptop and data card facilities
- Access to test centres
- Employee productivity monitoring

Mitigations Plans: Business Disruption(COVID 19)

Communication Department – Support Services Role

- Issue social distancing directives
- Online staff communication and training - person symptomatic, what must I do in my corridor, in my building, on my campus.
- Communicate cases, plans and mitigation measure timeously and frequently
- Timeous Response to media enquiries
- Work with IT to update website on a regular with relevant content to support information sharing for all stakeholders

Critical requirements to execute role during long term disruption

- Access to IT Systems
- Media Centre/Crises Control Centre
- Budget for communication design print and campaign and advertising
- Database of suppliers that will be used in procurement suppliers emergency list

Mitigations Plans: Business Disruption(COVID 19)

Finance Department : Support Services Role

- Budget allocation to COVID 19 procurement needs
- Support core business and the senior management team by maintaining a system of financial management that complies with the applicable legislation
- Payment of salaries and creditors payment
- Management of SAHPRA bank account
- Audit preparation for year end 31 March 2020

Critical requirements to execute role during long term disruption

- Printer with scanner and internet connectivity to pay suppliers
- Remote access to accounting system
- Electronic Authorization for Invoices
- Additional resource to ensure segregation of duties(approval invoice and processing of payments)

Mitigations Plans: Business Disruption(COVID 19)

Information Communication and Technology Departments – Support Services Role

- Provide ongoing technical support and access for IT systems and services – onsite and remotely
- Provide communication and information sharing platforms
- Enable and enhance infrastructure and service for remote connectivity.

Critical requirements to executive role during long term disruption

- Emergency funding as when required to establish additional remote service and tools of trade
- Regular access to CSIR premises(Server rooms)
- Continuity of 3rd part services
- Fully functioning datacenter(hardware)

Mitigations Plans: Business Disruption(COVID 19)

Building and Properties Actions – Support Services Team

- Sourcing of alternative work areas for contaminated office in liaison with CSIR.
- Enforcement of SAHPRA social distancing directives (i.e. review number of people occupying the same office and meeting rooms)
- Enforcement and monitoring of NDOH Directives (i.e. Provision of required PPE and Sanitary services for service link to frontline office/visitors)
- Implement daily temperature screening for at risk employees

Critical requirements to executive role during long term disruption

- Laptop, Data card and printer
- Emergency funding as when required to establish additional remote service and tools of trade
- Purchasing and distribution of PPEs at all sites
- Regular access to CSIR premises
- Continuity of all related 3rd party services

Mitigations Plans: Business Disruption(COVID 19)

3rd Party Services Actions – Procurement Team – Support Services

- Monitoring of inventory levels for essential goods(sanitary/stationery/ other PPEs)
- Request continuity plans for suppliers and contractors (IT/Security/Cleaning/equipment's)

Critical requirements to executive role during long term disruption

- Laptop and data card
- Printer
- Physical signature on quotations
- Emergency list of suppliers
- No alternative resource in procurement process
- Back up solution for procurement systems

Immediate Actions

Immediate Social Distancing practices

Ongoing communications and hygiene campaign

Restricted Travel

Sanitizer and PPE use across all buildings

Evolving response plan

Development of further response plans Training of core response teams

Test kits for SAHPRA employee use to be investigated

Staff online communication and training - person symptomatic, what must I do in my corridor, in my building, on my campus



Thank you