



SAHPRA- Update for Interaction with SAHPRA

The new coronavirus (COVID-19) is having an impact on business locally, regionally and globally. SAHPRA is by no means an exception.

In line with the National Lockdown please take note of the following:

- Most SAHPRA staff members will be working remotely.
- SAHPRA will continue working and its operations will continue

All information on SAHPRA business processes during COVID-19 may be found on SAHPRA's web page (<http://www.sahpra.org.za/be-prepared-for-covid-19/>)

- Please look at the SAHPRA Key Contacts page for contact information.
- Please note that all permits, certificates, licences, recommendations, resolutions and letters will not be collected from SAHPRA offices during this lockdown period. These will be e-mailed to applicants. These documents will not be embossed but will bear the CEO's signature. After the COVID-19 lockdown, you will receive further communication about this matter.
- Building 38, SAHPRA's document reception, as well as all other SAHPRA buildings will remain closed during the national lockdown.
- All meetings with external stakeholders will now be held on virtual platforms.

Key Contact Information:

Clinical Evaluation and Management:

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SECTION 21: Dr Shyamli Munbodh (shyamli.munbodh@sahpra.org.za)

Section21@sahpra.org.za for Section 21 queries

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NEW CLINICAL APPLICATIONS: Mahlodi Moropa (mahlodi.moropa@sahpra.org.za)

newmedicines@sahpra.org.za for new clinical applications queries

CLINICAL AMENDMENTS: Hitekani Mabunda (hitekani.mabunda@sahpra.org.za)

variations@sahpra.org.za for clinical amendments queries

VIGILANCE: Florah Matlala (mafora.matlala@sahpra.org.za)

adr@sahpra.org.za for ADR reporting

pvqueries@sahpra.org.za for Vigilance queries

CLINICAL TRIALS: Ms Kedibone Malatji (kedibone.malatji@sahpra.org.za) or Ms Dominicah Thosago (dominicah.thosago@sahpra.org.za)

ctcreponses@sahpra.org.za for Responses to new Clinical Trial applications and related queries

ctcamendments@sahpra.org.za for Protocol amendments, responses to amendments and related queries

ctcinvestigators@sahpra.org.za for Additional Investigators & Sites, responses to additional Investigators & Sites and related queries

ctcbeprotocols@sahpra.org.za for Bioequivalence studies, BE amendments, responses to BE studies and related queries

ctcnotifications@sahpra.org.za for Notifications and related queries

ctcsaes@sahpra.org.za for Individual Patient Serious Adverse Events and related queries

ctcguidelines@sahpra.org.za for Clinical Trials conduct guidelines and related queries

Pharmaceutical Evaluations:

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Pre-Registration:

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073 8512416

Post Registration:

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081 307 6910

Complementary Medicines:

PEM: Complementary medicines Section 21

CM21@sahpra.org.za

PEM: Complementary unit Licensing

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Contact telephone number: 0711343709

Biologicals:

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Veterinary Medicines:

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Inspectorate and Regulatory Compliance:

Ms Andrea Julsing

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For all medical device queries related to COVID-19: MDcovid@sahpra.org.za

June Searela june.searela@sahpra.org.za – 072 828 2416 - General licensing queries

Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za – 071 302 0409 - Applications for licences (for medical devices related to COVID-19)

Khanyisile Nkuku Khanyisile.Nkuku@sahpra.org.za – 081 854 7109 – Applications for licences (for medical devices related to COVID-19)

Daphne Fafudi Mokgadi.Fafudi@sahpra.org.za – 066 301 1878 - Releases (Port Health)

Health Products Authorisation:

Ms Santhani Chetty

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applicationnumbers@sahpra.org.za – request for an application number/identifier for a new product registration application (eCTD or eSubmission)

certificationvariations@sahpra.org.za – queries for BAU certification variation applications

newmedicines@sahpra.org.za – queries for BAU new medicine applications

variations@sahpra.org.za – queries for BAU variation applications

Backlog Project:

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