



## **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.

### **Priority Process Guidance for New Medicine Registration Applications**

**Applicants** who require to submit a new application for medicine registration must follow the following process:

- Make an email request for an application number to [applicationnumbers@sahpra.org.za](mailto:applicationnumbers@sahpra.org.za).
- The applications related to COVID-19 should have the following information:
  - Basic information (refer to submission guidelines 2.23 or 2.58)
  - Motivation for COVID-19 use
  - Information on Name and Address of API source/s

- Information on the Manufacturer, Packer, Laboratory of the final packaged product
- cGMP certificates for the sites requested
- The applicant will be given an application number and fees payable within five days
- For the process of submission refer to section on “electronic submission of documents” in the section below.

### **Priority Process Guidance for Variations**

**Applicants** who require their variations to be considered priority review must follow the following process:

- Make an email request to Quality variations unit ([PriorityQvariations@sahpra.org.za](mailto:PriorityQvariations@sahpra.org.za)) for Quality changes, and [PriorityIvariations@sahpra.org.za](mailto:PriorityIvariations@sahpra.org.za) for Inspectorate and [PriorityCvariations@sahpra.org.za](mailto:PriorityCvariations@sahpra.org.za) for Clinical for priority review which contains the proprietary name, application number, Applicant details (name, email, contact number), what the change is required and the motivation (e.g supplier in country with lock down; drug used in standard treatment guideline for COVID; is used in clinical management of patients; tender)
- The relevant Variations unit will respond by giving the applicant a reference number to submit the variation. This reference number should be included in cover letter of the application
- For the process of submission refer to section on “electronic submission of documents” in the section below.

### **Electronic Submission of Documents:**

For Business Continuity following the COVID-19 National Lockdown, SAHPRA has established an online facility for large electronic submissions of eCTDs and eSubmissions.

For more information and to request access to the SAHPRA document upload system please send an email to the applicable address below:

For Backlog-related submissions e-mail:

[backlog@sahpra.org.za](mailto:backlog@sahpra.org.za)

For Business-As-Usual submissions e-mail:

[newmedicines@sahpra.org.za](mailto:newmedicines@sahpra.org.za)

OR

[Variations@sahpra.org.za](mailto:Variations@sahpra.org.za)

### **Process Guidance for Post Importation Testing Exemption (PITE)**

Applicants who intend to obtain Post Importation Testing Exemption requests should submit as per the SAHPRA PITE guidelines to the respective units namely;

1. Inspectorate (small molecules) to [Susan.Khoza@sahpra.org.za](mailto:Susan.Khoza@sahpra.org.za)
2. Biologicals to [biologicals@sahpra.org.za](mailto:biologicals@sahpra.org.za)

Applicants requiring post importation testing exemption for the first time based on COVID 19 situation are required to submit the following:

- Application letter on company letterhead with motivation
- Module 1 application 1.2.1
- Proof of payment
- Temperature data (transport temperature logs)
- CoA of manufacturer
- Stability data
- For Biological products - Data from a minimum of five temperature printouts are required, giving an account of the same product or five different biological products, provided that the products require the same storage conditions, and provided that the products are dispatched from the same site but by different shipments.

In the case of a renewal of existing post importation testing exemptions, applicants must provide a copy of the previous PITE approval and include information as per the current PITE guidelines.

## **Key Contact Information:**

### **Clinical Evaluation and Management:**

082 302 0222

**SECTION 21:** Dr Shyamli Munbodh ([shyamli.munbodh@sahpra.org.za](mailto:shyamli.munbodh@sahpra.org.za))

[Section21@sahpra.org.za](mailto:Section21@sahpra.org.za) for Section 21 queries

072 134 4546

063 771 8906

**NEW CLINICAL APPLICATIONS:** Mahlodi Moropa ([mahlodi.moropa@sahpra.org.za](mailto:mahlodi.moropa@sahpra.org.za))

[newmedicines@sahpra.org.za](mailto:newmedicines@sahpra.org.za) for new clinical applications queries

**CLINICAL AMENDMENTS:** Hitekani Mabunda ([hitekani.mabunda@sahpra.org.za](mailto:hitekani.mabunda@sahpra.org.za))

[variations@sahpra.org.za](mailto:variations@sahpra.org.za) for clinical amendments queries

**VIGILANCE:** Florah Matlala ([mafora.matlala@sahpra.org.za](mailto:mafora.matlala@sahpra.org.za))

[adr@sahpra.org.za](mailto:adr@sahpra.org.za) for ADR reporting

[pvqueries@sahpra.org.za](mailto:pvqueries@sahpra.org.za) for Vigilance queries

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

[ctcresponses@sahpra.org.za](mailto:ctcresponses@sahpra.org.za) for Responses to new Clinical Trial applications and related queries

[ctcamendments@sahpra.org.za](mailto:ctcamendments@sahpra.org.za) for Protocol amendments, responses to amendments and related queries

[ctcinvestigators@sahpra.org.za](mailto:ctcinvestigators@sahpra.org.za) for Additional Investigators & Sites, responses to additional Investigators & Sites and related queries

[ctcbeprotocols@sahpra.org.za](mailto:ctcbeprotocols@sahpra.org.za) for Bioequivalence studies, BE amendments, responses to BE studies and related queries

[ctcnotifications@sahpra.org.za](mailto:ctcnotifications@sahpra.org.za) for Notifications and related queries

[ctcsaes@sahpra.org.za](mailto:ctcsaes@sahpra.org.za) for Individual Patient Serious Adverse Events and related queries

[ctcguidelines@sahpra.org.za](mailto:ctcguidelines@sahpra.org.za) for Clinical Trials conduct guidelines and related queries

**Pharmaceutical Evaluations:**

Ms Silverani Padayachee 082

688 9955

[Silverani.padayachee@sahpra.org.za](mailto:Silverani.padayachee@sahpra.org.za)

**Pre-Registration:**

[PEMPre-reg@sahpra.org.za](mailto:PEMPre-reg@sahpra.org.za)

073 8512416

**Post Registration:**

[PriorityQvariations@sahpra.org.za](mailto:PriorityQvariations@sahpra.org.za)

081 307 6910

**Complementary Medicines:**

PEM: Complementary medicines Section 21

[CM21@sahpra.org.za](mailto:CM21@sahpra.org.za)

PEM: Complementary unit Licensing

[admin@sahpracm.org.za](mailto:admin@sahpracm.org.za)

Contact telephone number: 0711343709

**Biologicals:**

[biologicals@sahpra.org.za](mailto:biologicals@sahpra.org.za)

[0713022135](tel:0713022135)

**Veterinary Medicines:**

[pervetS21@sahpra.org.za](mailto:pervetS21@sahpra.org.za)

079 400 5796

**Inspectorate and Regulatory Compliance:**

Ms Andrea Julsing

082 062 2594

[andrea.julsing@sahpra.org.za](mailto:andrea.julsing@sahpra.org.za)

For all medical device queries related to COVID-19: [MDcovid@sahpra.org.za](mailto:MDcovid@sahpra.org.za)

June Searela [june.searela@sahpra.org.za](mailto:june.searela@sahpra.org.za) – 072 828 2416 - General licensing queries

Matlapeng Shabalala [Matlapeng.Shabalala@sahpra.org.za](mailto: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](mailto: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](mailto:Mokgadi.Fafudi@sahpra.org.za) – 066 301 1878 - Releases (Port Health)

**Health Products Authorisation:**

Ms Santhani Chetty

071 386 0867

[Santhani.chetty@sahpra.org.za](mailto:Santhani.chetty@sahpra.org.za)

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

[certificationvariations@sahpra.org.za](mailto:certificationvariations@sahpra.org.za) – queries for BAU certification variation applications

[newmedicines@sahpra.org.za](mailto:newmedicines@sahpra.org.za) – queries for BAU new medicine applications

[variations@sahpra.org.za](mailto:variations@sahpra.org.za) – queries for BAU variation applications

**Backlog Project:**

Mr Mabatane Malatji

079 503 5139

[backlog@sahpra.org.za](mailto:backlog@sahpra.org.za)