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.
- 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) for Quality changes, and PriorityIvariations@sahpra.org.za for Inspectorate and 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

For Business-As-Usual submissions e-mail:

newmedicines@sahpra.org.za

OR

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
2. Biologicals to 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
- Temptale 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)

Section21@sahpra.org.za for Section 21 queries

072 134 4546

063 771 8906

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

ctcresponses@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:

Ms Silverani Padayachee

082 688 9955

Silverani.padayachee@sahpra.org.za

Pre-Registration:

PEMPre-reg@sahpra.org.za

073 8512416

Post Registration:

PriorityQvariations@sahpra.org.za

081 307 6910

Complementary Medicines:

PEM: Complementary medicines Section 21

CM21@sahpra.org.za

PEM: Complementary unit Licensing

admin@sahpracm.org.za

Contact telephone number: 0711343709

Biologicals:

biologicals@sahpra.org.za

0713022135

Veterinary Medicines:

pervetS21@sahpra.org.za

079 400 5796

Inspectorate and Regulatory Compliance:

Ms Andrea Julsing

082 062 2594

andrea.julsing@sahpra.org.za

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 Khanyisle.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

071 386 0867

Santhani.chetty@sahpra.org.za

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:

Mr Mabatane Malatji

079 503 5139

backlog@sahpra.org.za