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Regulatory and Licensing requirements for Sanitisers

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Outline

- SAHPRA Regulatory Mandate
- Legislation
- Classification of sanitisers/ disinfectants
  - Hand Sanitisers/ Rubs
  - Disinfectants/ Germicide
- Current Regulatory and Licencing Requirements
- Amended Regulatory Pathway
- Questions

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SAHPRA's Public Health and Regulatory Mandate

Two distinct objectives:

- Protect patients against harmful or ineffective medicines/ medical devices
  - Gatekeeper function with obligation to apply stringent standards of assessment and to restrict availability where deemed necessary.
- Protect patients against the consequences of untreated disease
  - Enabling availability to ensure that patients have timely access to safe and effective medicines/ medical devices

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Legislation

- Disinfectant/ Sanitising products are regulated by 5 different Acts and the regulations thereof:
  - The Medicines and Related Substances Act, 1965 (Act 101 of 1965)
  - The Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 as amended (FCD Act);
  - The Standards Act, Act 8 of 2008 (Standards Act);
  - The National Regulator for Compulsory Specifications Act 5 of 2008 (NRCS Act); and
  - The Legal Metrology Act 9 of 2014.

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Classification of Disinfecting/ Sanitising Products

- Disinfectant/ Sanitising products may fall into various regulatory groups depending on the:
  - Application surface (human skin or inanimate surface)
  - Environment the sanitiser is used in (place of use)
  - Intended use and function; and
  - Composition
- Hand Sanitisers and Hand Gels; Surface Sanitisers; Antiseptics; Disinfectants; and Germicides

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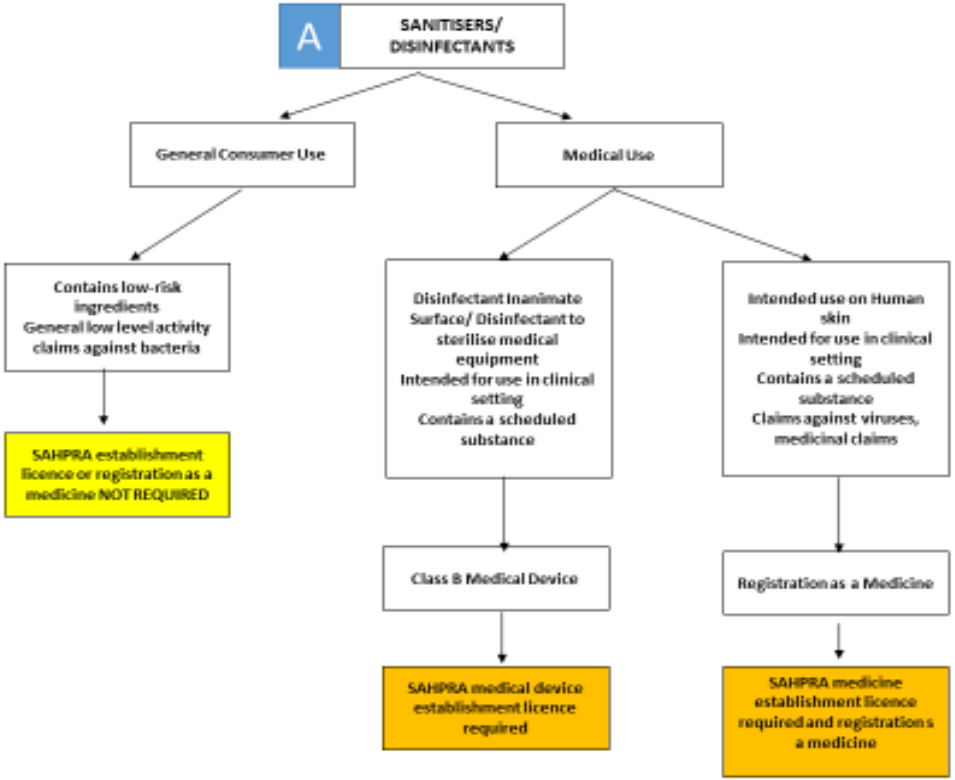
Classification of Disinfecting/ Sanitising Products



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Hand Sanitisers/ Rubs

- For use on human skin
- Contain antiseptic ingredients used to kill microorganisms or prevent the growth of microorganisms
- Can be handwashes for use **with** water or handrubs for use **without** water
- “Rub” or “Leave on” products primarily used to sanitise the skin, when soap and water are not available, and are left on and not rinsed off with water.

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When are Hand Sanitisers/ Rubs classified as General Consumer Products?

- Do not contain a substance listed in the Schedules to the Medicines Act (low-risk ingredients); **and**
- Make general low level activity claims against bacteria (for example, kills 99.9 % of bacteria, germs).
- **Controlled under the FCD Act**
- Hand rubs must comply with relevant SANS, equivalent global standards, and the Legal Metrology Act as well as the relevant labelling and compositions requirement in the FCD Act.
- **Alcohol based hand sanitisers** must comply **with SAN490:2013**

When are Hand Sanitisers/ Rubs classified as Medicines?

- Contain a substance listed in the Schedules to the Medicines Act e.g. chlorhexidine; **or**
- Claim activity (treat/ prevent) against viruses, fungi or other microbial organisms (other than bacteria); **or**
- Intended for use in connection with disease, disorders or medical conditions; **or**
- Intended for use in clinical/ hospital environments, aged-care facilities

Requires registration as a medicine and the manufacturer to be licensed in terms of Section 22C(1)(b) of the Medicines Act

Disinfectants and Germicides

- For use on inanimate surfaces
- **Disinfectant**: An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores.

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When are Disinfectants classified as General Consumer Products?

- Used on inanimate surfaces in low risk areas **e.g.** the home, public venues (schools, restaurants), **and**
- Do not contain a substance listed in the Schedules to the Medicines Act (low-risk ingredients);
- **Controlled under the FCD Act,**
- Must comply with the requirements of the "Compulsory specification for chemical disinfectants VC8054" as set out by the NRCS, the Legal Metrology Act, 2014 (Act 09 of 2014) as well as all relevant SANS standards.

When are Disinfectants classified as Medical Devices?

- Used on inanimate surfaces; **and** Intended for use in high risk areas **e.g.** clinical/ hospital environments, aged-care facilities; **or**
- Used on inanimate surfaces **and** contains a substance listed in the Schedules to the Medicines Act e.g. chlorhexidine; **or**
- Used to clean and sterilise medical devices/ equipment
- **Controlled under the Medicines Act,**
- Classified as a **Class B** Medical Device
- Manufacturers, distributors and wholesalers of Class B medical devices must comply with the SAHPRA licensing requirement

Where the intended use or claim for a sanitiser/disinfectant lies both in a low risk area and a high risk area, the product will fall under the regulatory ambit of the Medicines Act; and fall within the mandate of the SAHPRA.

SAHPRA's Current Licence and Registration Requirements Medicines

- Any company or individual intending to manufacture, distribute (import/export) or wholesale a medicine is required, in terms of **Section 22C** of the Medicines Act to be **licensed** by SAHPRA.
- Any company or individual intending to manufacture, distribute (import/export) or wholesale a medicine is required to **register** said medicine in terms of **Section 15** of the Medicines Act.
- Individuals/companies **may not** manufacture/distribute/wholesale medicines without a valid SAHPRA licence and a valid registration for the medicine.

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SAHPRA's Current Licence Requirements Medicines

The following documents must be submitted upon application to SAHPRA for a new medicine establishment licence (regulation 23):

i. Relevant Licence Application and Cover Letter

ii. Documentary proof of-

- *the particulars of the owner of the business; registration of the responsible pharmacist with the South African Pharmacy Council;*
- *qualifications of key personnel responsible for the manufacture. storage, distribution and sale*
- *the ability to comply with good manufacturing, wholesaling or distribution practices, which must include-*
  - *(aa) a copy of a local area plan of the location of the business premises*
  - *(bb) a floor plan of the building in which the business premises are situated*
  - *(cc) a plan of the actual layout of the business premises;*
  - *(dd) an inventory of equipment to be used in conducting the business; and*
  - *(ee) a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines, or Scheduled substances to be manufactured or distributed and sold;*

The applicant shall-

(aa) appoint, and designate as such a responsible pharmacist;

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SAHPRA's Current Licence Requirements Medicines

- Registration requirements are as per Regulation 9 – 21 of the General Regulations

REGISTRATION OF MEDICINES

9. Categories and classification of medicines
10. Labelling of medicines intended for human use
11. Professional Information for medicines for human use
12. Patient information leaflet
13. Labelling for veterinary medicines
14. Professional information for veterinary medicines
15. Batch release for biological medicines
16. Application for the registration of a medicine
17. Particulars to be published in respect of applications received for registration in terms of section 14(3)
18. Information that must appear in register for medicines
19. Transfer from register for medicines to register for medical devices or IVDs
20. Application for amendment to the register for medicines
21. Certificate of registration

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SAHPRA's Current Licence Requirements
Medical Devices

- Any company or individual intending to manufacture, distribute (import/export) or wholesale a medical device/IVD is required, in terms of Section 22C of the Medicines Act to be licensed by SAHPRA.
- Individuals/companies **may not** manufacture/distribute/wholesale medical devices without a valid SAHPRA medical device establishment licence.

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SAHPRA's Current Licence Requirements
Medical Devices

The following documents must be submitted upon application to SAHPRA for a new medical device establishment licence:

i. Cover letter on company letter indicating intention to apply for a new SAHPRA licence.
ii. Licence Application (6.21 Manufacturer / 6.22 Distributor / 6.26 Wholesaler)
iii. Proof of Payment (Manufacturer: R 23 980 / Distributor or Wholesaler: R 14 300)
iv. Curriculum Vitae of the Authorised Representative

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SAHPRA's Current Licence Requirements
Medical Devices

ii. Licence Application (6.21 Manufacturer / 6.22 Distributor)

Different sections and tabs

- Section 1 – 3 General Information
- Section 4.1 – 4.4 Product Listings
- Section 5 - 15 Manufacturing/ Packing/ Lab Analysis
- Section 16 Storage
- Section 17.1 – 17.2 Export
- Section 18 Activities
- Section 19 – 21 Personnel Information
- Section 22 QMS
- Section 23 Declaration

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SAHPRA's Current Licence Requirements
Medical Devices

4.1	LIST OF NON-IVD MEDICAL DEVICES MANUFACTURED in SOUTH AFRICA										
	LOCAL SA Person [COMPANY] Name:			"NON-IVD" = Medical device which is not an IVD							
		GMDN = Global Medical Device Nomenclature				For Class C and Class D Medical Devices (NON - IVDs) - where held					
No.	COMPANY NAME	GMDN CODE	GMDN Descriptor	Name and or group or family of the medical device	SA Risk Classification: A or B or C or D	FDA PMA Ref No.	CE Marking Ref No.	TGA Reg No.	Health Canada Reg No.	Japan Reg. No.	ANVISA Reg. No
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											

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SAHPRA's Current Licence Requirements Medical Devices

v. Quality Manual (as per quality manual guideline 8.07)

Minimum requirements

- Company Details
- Scope and span on QMS
  - details and status of certification – e.g. ISO13485
  - Policies and procedures e.g. adverse event reporting, recalls, traceability, storage
  - Type and classification of medical devices listed
  - Organogram
  - External/ third party providers
- Site Information
  - Address, contact details, contact persons
  - Access control, security control
  - Details of structure, and size of different allocated spaces
  - HVAC systems
  - equipment

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SAHPRA's Current Licence Requirements
Medical Devices

vi. **Supportive evidence for each Class A (measuring and/or sterile), B, C and/or Class D PPE listed including:**

- Evidence of pre-market approval/registration/evidence of emergency use authorisation for each listed PPE from at least one of the six jurisdictions recognised by SAHPRA (not mandatory for Class A and B devices)
- Certificate of Free Sale confirming evidence that each listed PPE is legally sold or distributed
- Evidence of ISO13485:2016 certification of the original manufacturer for each listed PPE
- Copy of Instructions for Use (IFU) for each listed PPE
- Copy of labelling and packaging of each listed PPE
- Evidence of compliance against the minimum requirements and/or certification against relevant standards and specifications as determined by the South African Bureau of Standards (SABS) and/or the National Regulator for Compulsory Specifications (NRCS), or compliance to relevant global standards

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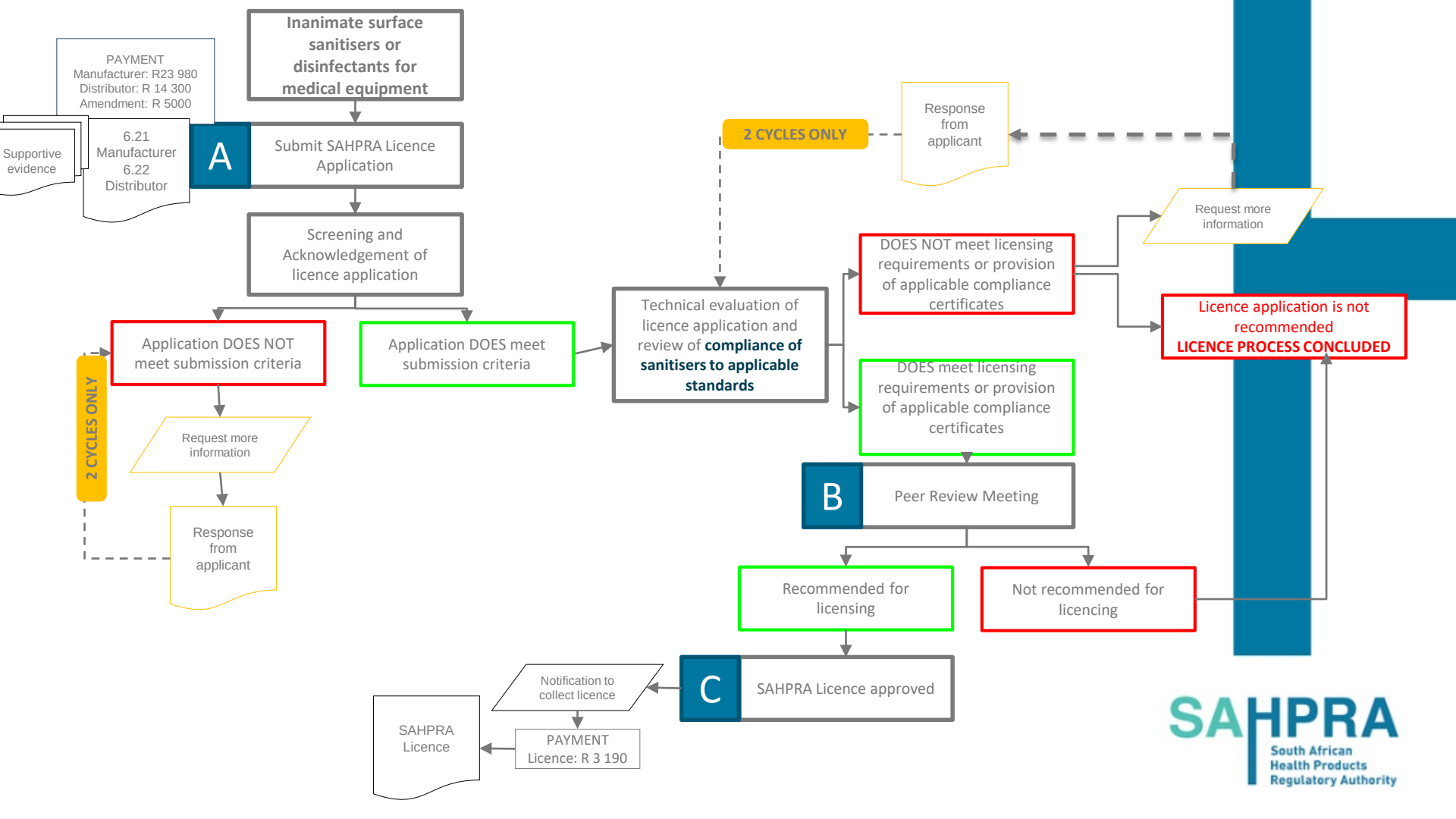
Inanimate surface sanitisers or disinfectants for medical equipment
PAYMENT
Manufacturer: R23 980
Distributor: R 14 300
Amendment: R 5000
Supportive evidence
6.21 Manufacturer
6.22 Distributor
A
Submit SAHPRA Licence Application
Screening and Acknowledgement of licence application
Application DOES NOT meet submission criteria
2 CYCLES ONLY
Request more information
Response from applicant
Application DOES meet submission criteria
Technical evaluation of licence application and review of compliance of sanitisers to applicable standards
2 CYCLES ONLY
Response from applicant
DOES NOT meet licensing requirements or provision of applicable compliance certificates
Request more information
Licence application is not recommended
LICENCE PROCESS CONCLUDED
DOES meet licensing requirements or provision of applicable compliance certificates
B
Peer Review Meeting
Recommended for licensing
Not recommended for licencing
C
SAHPRA Licence approved
Notification to collect licence
PAYMENT
Licence: R 3 190
SAHPRA Licence
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Alternative Medicine Registration and Licensing Pathway for Alcohol-based hand sanitisers during Covid-19

- The proposed alternative pathway to licensing would be specific to local manufacturers to manufacture hand sanitiser/handrub
- In response to the anticipated shortage of alcohol-based hand sanitisers for use in the health care system as a result of the outbreak of the Covid-19 pandemic, the Minister of Health has, under specific conditions:
  - **excluded** certain alcohol-based handrubs used or purporting to be suitable for use to prevent or treat infection within a clinical environment from the provisions of Section 14(1) of the Medicines Act, and regulations 11 and 12 of the General Regulations made in terms of the Act (Government Notice No. R. 859 of 25 August 2017) (the General Regulations), and
  - **excluded** manufacturers licenced in terms of section 22C(1)(b) of the Medicines Act, of the mentioned alcohol-based handrubs from regulations 23(1)(c)(ii), 23(1)(c)(iv), and 23(2)(aa) of the General Regulations

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Alternative Medicine Registration and Licensing Pathway for Alcohol-based hand sanitisers during Covid-19

- Section 14(1) of the Act refers to the registration of a medicine
- Regulation 11 and 12 refer to the professional information and patient informational leaflet, respectively.
- Regulation 23 refers to:
  - the licence to manufacture, import, export, act as a wholesaler or distribute medicines to scheduled substances;
  - the requirement for a responsible pharmacist
  - registration of the responsible pharmacist,
  - Compliance with GMP

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Alternative Medicine Registration and Licensing Pathway for Alcohol-based hand sanitisers during Covid-19

- Provided that the application for a licence in terms of section 22C(1)(*b*) of the Act and regulation 23, to manufacture, import or distribute the alcohol-based handrubs ,shall be accompanied by the following documentary evidence:
  - Site Master File (SMF)
  - a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of the said handrubs; including procedures for the conduct of analytical tests;
  - an inventory of equipment to be used to manufacture said handrubs;
  - the master batch manufacturing record;
  - certificate of analysis; and

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Alternative Medicine Registration and Licensing Pathway for Alcohol-based hand sanitisers during Covid-19

- a signed declaration by the **responsible person** of the holder of the licence: -

- (aa) that the hand rub is prepared according to the “Guide to Local Production: WHO-recommended Handrub Formulations”;
- (bb) that the hand rub is tested according to and compliant with the test methodology provided in the South African National Standard (SANS) 490:2013 “Disinfectant alcohol-based handrub”;
- (cc) that the concentration of ethyl alcohol or isopropyl alcohol used will be verified for each batch using gas chromatography, alcoholmeter, hydrometer, or other chemical analysis of equivalent or greater accuracy;
- (dd) that the hand rub is manufactured under sanitary conditions using equipment that is well maintained and fit for purpose;
- (ee) that records relating to the manufacture of the hand rub will be kept by the manufacturer; and
- (dd) that the hand rub is safe for its intended use.

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Additional Conditions to the Licence

- The license holder is only permitted to manufacture the alcohol-based handrub according to the WHO-recommended Handrub Formulations as provided for in the “Guide to Local Production: WHO-recommended Handrub Formulations, and no other medicines or scheduled substance.
- The licence will be valid for up to twelve (12) months and may be withdrawn or extended by the SAHPRA at any time.
- The licence holder is required to provide full details to SAHPRA of all adverse incidents occurring in relation to the use of the alcohol-based hand rub;
- In order to continue to be manufactured and sold beyond the expiry of the licence, the licence holder will be required to meet all the requirements, including GMP compliance, and submit all documentary evidence as per the normal licensing process.

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THANK YOU