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The role of SAHPRA and the licensing process for PPE medical device establishments

NIOH Webinar: Covid-19 workplace health risk assessment
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Outline

- SAHPRA
- SAHPRA Regulatory Mandate
- PPE as medical devices?
- Classification of PPE regarded as medical devices
  - Masks
  - Gloves
  - Aprons, protective outer wear
  - sanitisers
- Licencing Requirements
- Expedited Pathway
- Questions

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South African Health Products Regulatory Authority (SAHPRA)

- Replaced the Medicines Control Council (MCC) on the 1 February 2018
- Schedule 3A independent public entity with operational autonomy and accountability
- Responsible for the regulation of all medicines, including complementary medicines, medical devices and radiation control
- Mandated and governed by the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, and the schedules and regulations thereto, together with the guidelines made in terms of this Act.

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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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Is PPE regarded as medical devices?

- Any personal protective equipment (PPE) that fall within the definition of a medical device is regulated by SAHPRA as a medical device under the ambit of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
- When indicated/ intended for use in a medical or healthcare environment
- When making medical claims
- Eg. Masks, gloves, gowns, surface sanitisers

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Why are PPE regarded as medical devices?

- To ensure the quality, safety and performance of the device
- Ensure the medical professionals and the public are protected.

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Classification of PPE regarded as Medical Devices

- In the wake of the coronavirus crisis, and with the increase in the need and use of devices and equipment to prevent the spread of coronavirus, it is paramount that the regulatory status of such devices and equipment is clearly articulated

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Classification of PPE regarded as Medical Devices

General, Medical (Surgical) Face Masks and Respiratory Protective Devices (Respirators)

- Face masks fall into different regulatory groups depending on the type of face mask and intended use of the face mask:
  - General,
  - Medical (Surgical) Masks Non-Sterile, (Class A)
  - Medical (Surgical) Masks Sterile, and (Class A Sterile)
  - Respirator Masks. (Class B)

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ANNEXURE A: SUMMARY OF FACE MASKS

	Cloth mask	Non-Sterile Medical (Surgical) Mask	Non-Sterile Medical (Surgical) Mask	Sterile Medical (Surgical) Mask	Dust Mask	Respirator Mask	Respirator Mask (Particle Filtering Half Mask
							
Examples		1-ply, 2-ply or 3-ply masks	3-ply masks	3-ply masks		N95, KN95	N95, KN95
Classification	Non-medical General	Non-medical General	Class A medical device	Class A medical device (Sterile)	Non-medical General	Class B medical device	Non-medical e.g. mining industry
SAHPRA manufacturer, distributor, wholesaler licence	No	No	No Exemption from licensing requirement for non-sterile Class A medical devices	Yes	No	Yes	No
NRCS sales permit/ authorisation (LOA)	No	No	No	No	No	Yes	Yes
Specification/ Standards/ Other Legislation	None Department of Health guideline on the "Use of Cloth Face-Masks by Members of the General Public in South Africa during the COVID-19 Pandemic"	None	Yes SANS 1866-1 :2018 Legal Metrology Act,2014 (Act 09 of 2014), in terms of packaging and labelling.	Yes SANS 1866-1 :2018 Legal Metrology Act,2014 (Act 09 of 2014), in terms of packaging and labelling.	None	Yes. SANS 1866-2 2018 VC8072:2011 - Compulsory Specification for respiratory protective devices	Yes. SANS 1866-2 2018 VC8072:2011 - Compulsory Specification for respiratory protective devices

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	Cloth mask	Non-Sterile Medical (Surgical) Mask	Non-Sterile Medical (Surgical) Mask	Sterile Medical (Surgical) Mask	Dust Mask	Respirator Mask	Respirator Mask (Particle Filtering Half Mask
							
Intended use and purpose	Non-medical environment Respiratory hygiene and extension of coughing and sneezing etiquette	Non- medical environment Respiratory hygiene and extension of coughing and sneezing etiquette Capturing large particles or droplets from the wearer and preventing them from being spread to their environment	Clinical/ Healthcare environment Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Clinical/ Healthcare environment Fluid resistant and provides the wearer protection against large-particle droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Non-medical and Non-hazardous environments One way protection only capturing large particles or droplets from the wearer and preventing them from being spread to their environment	Clinical/ Healthcare environment Reduces wearer's exposure to particles including small particle aerosols and large droplets Protects the patient from the wearer's respiratory emissions.	Non-medical environment Hazardous environment Reduces wearer's exposure to particles including small particle aerosols and large droplets
Face seal fit	Loose-fitting	Loose-fitting	Loose-fitting	Loose-fitting	Loose-fitting	Tight-fitting	Tight-fitting
Filtration	None	None	Does **NOT** provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Does **NOT** provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	None	Filters out at least 95% of airborne particles including large and small particles	Filters out at least 95% of airborne particles including large and small particles

	Cloth mask	Non-Sterile Medical (Surgical) Mask	Non-Sterile Medical (Surgical) Mask	Sterile Medical (Surgical) Mask	Dust Mask	Respirator Mask	Respirator Mask (Particle Filtering Half Mask
							
Use limitations	Wash and iron after each use Discard when mask is worn out or damaged	Single-use only Disposable	Single-use only Disposable Discard after each patient encounter.	Single-use only Disposable Discard after each patient encounter.	Disposable	Single use only Disposable Discard after each patient encounter.	Disposable Discard when mask is damaged or deformed; or breathing becomes difficult

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Classification of PPE regarded as Medical Devices

Surgical, Examination and General Gloves

- Gloves fall into different regulatory groups depending on the intended use of the gloves.
  - General gloves (labs, etc)
  - Examination gloves (non sterile) **(Class A)**
  - Examination gloves , surgical (sterile), and **(Class B)**
- Sterile and non-sterile gloves must equally comply with and be tested according to the test methodology provided in:
  - **SANS11193-1:2010** "Single-use medical examination gloves Part 1: Specification for gloves made from rubber latex or rubber solution" and
  - **SANS68:2003** "Single-use sterile rubber surgical gloves - Specification" or equivalent international standards.

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Classification of PPE regarded as Medical Devices

Gowns, Aprons, overshoe covers, Protective outerwear

- fall into different regulatory groups depending on the intended use of the gown.
  - General gowns/aprons
  - Surgical gowns (non sterile) **(Class A)**
  - Surgical gowns (sterile) **(Class A Sterile)**
- Comply with and be tested according to the test methodology provided in:
  - **ISO 13688:2013** "Protective clothing"

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Classification of PPE regarded as Medical Devices

Surface Sanitisers

- Disinfectants and germicides used on inanimate surfaces in low risk areas are controlled under the ambit of the FCD Act, and fall within the mandate of the Directorate: Environmental Health within the Department of Health.
- These products 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 9 of 2014) as well as all relevant SANS.
- Disinfectants, antiseptics and germicides used on inanimate surfaces in areas of high risk are controlled as **CLASS A or B** medical devices

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SAHPRA's Current Licence Requirements

- 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

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

- Cover letter on company letter indicating intention to apply for a new SAHPRA licence.
- Licence Application (6.21 Manufacturer / 6.22 Distributor / 6.26 Wholesaler)
- Proof of Payment (Manufacturer: R 23 980 / Distributor or Wholesaler: R 14 300)
- Curriculum Vitae of the Authorised Representative
- Quality Manual
- Supportive evidence for each Class C and 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
  - 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
- Supportive evidence for each Class A (measuring and/or sterile), B, C and/or Class D PPE listed including:
  - 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).

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SAHPRA's Licence Requirements

Wholesaler

- Appoint qualified personnel
- Demonstrate compliance with GWP/ GDP
- Licence application should include:
  - SMF
  - Product listing stored, transported, dispatched or sold

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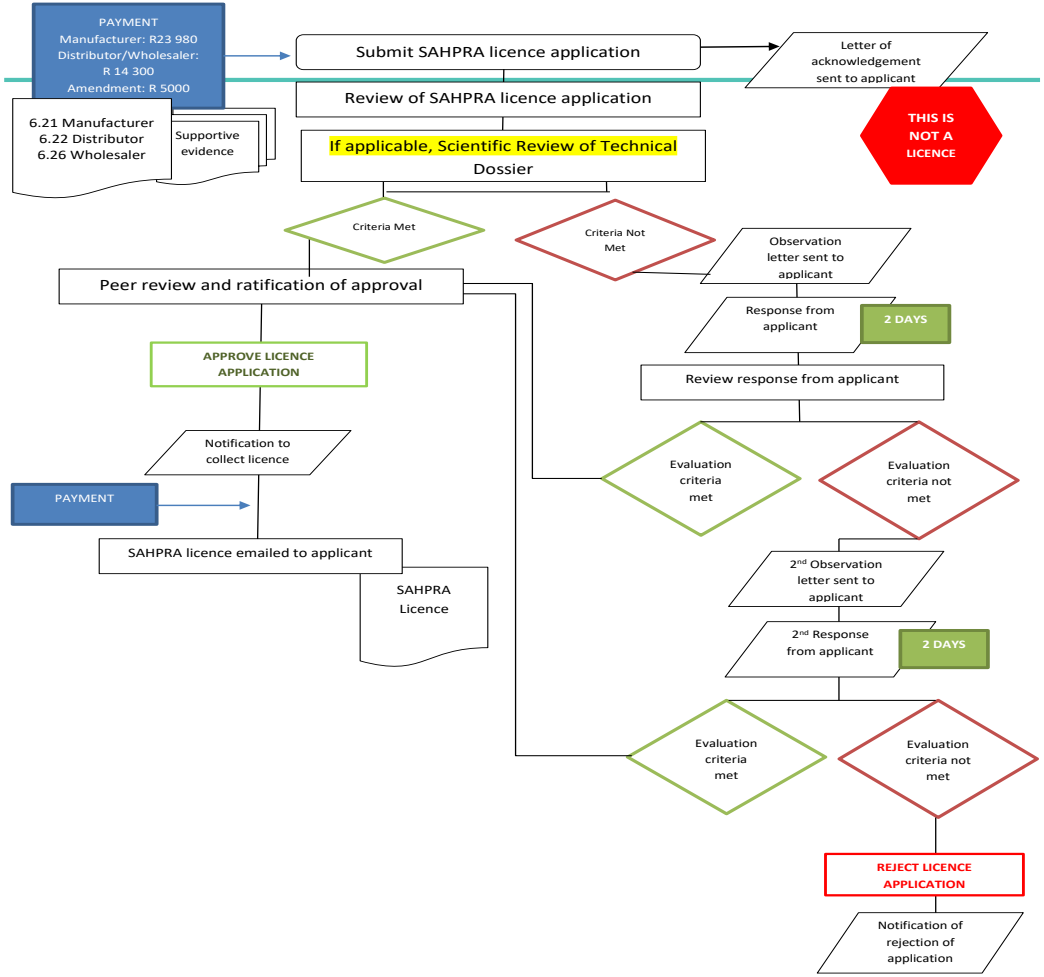
ANNEXURE 1: PROCESS FLOW FOR LICENCE APPLICATION PROCESS



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Expedited Pathway during Covid-19

- SAHPRA)is providing active support for monitoring a number of issues relating to medical devices including in-vitro diagnostics (IVDs) in response to the novel coronavirus
- Through the use of expedited regulatory pathways SAHPRA is able to help strengthen the nation's public health protections by facilitating the availability and use of medical devices needed during public health emergencies.
- SAHPRA is committed to reducing the time taken to review and process licence applications for medical device establishments from 6 – 8 weeks to 10 – 15 working days.

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THANK YOU