SAHPRA
South African
Health Products
Regulatory Authority

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Communication to Stakeholders 08 September 2020

MD025: Licensing and Regulatory requirements for the manufacture and distribution of medical and respirator masks during Covid-19

Background

1. The supply of sub-standard medical masks and respirator masks (FFP1 and FFP2) to the healthcare professionals during the Covid-19 pandemic, and the failure of these masks to meet the applicable compliance standards, has prompted SAHPRA to draft an amendment to the licensing and regulatory requirements for the manufacture, importation and distribution of said masks.

Current Regulatory and Licensing Requirements

2. Masks, fall into different regulatory groups depending on the type of face mask and intended use of the face mask:
    a. General,
    b. Medical (Surgical) Masks Non-Sterile, (Class A)
    c. Medical (Surgical) Masks Sterile, and (Class A Sterile)
    d. Respirator Masks. (Class B)
3. Masks are regarded as medical devices and are regulated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Medicines Act) when they are intended for use in a healthcare, clinical or high-risk setting and make claims to protect the patient from the wearers respiratory emissions or to protect the wearer from droplets or splatter.
4. 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.
5. Individuals/companies **may not** manufacture/distribute/wholesale medical devices without a valid SAHPRA medical device establishment licence.
6. The Authority regards it as a minimum requirement for sale of masks as medical devices on the South African market that the-
    a. medical device establishment responsible for the manufacture, import, export or distribution of the mask is licensed by the SAHPRA; and

b. mask is specified in terms of regulation 5(1)(d) of the Regulations Related to Medical Devices made in terms of the Medicines Act.
c. Mask meets the specified minimum specifications i.e. SANS1866:1, SANS1866:2, equivalent global standards

7. The following documents must be submitted upon application to SAHPRA for a new medical device establishment licence:
   a. Cover letter on company letter indicating intention to apply for a new SAHPRA licence.
   b. Licence Application (6.21 Manufacturer / 6.22 Distributor / 6.26 Wholesaler)
   c. Proof of Payment (Manufacturer: R 23 980 / Distributor or Wholesaler: R 14 300)
   d. Curriculum Vitae of the Authorised Representative
   e. Quality Manual
   f. Supportive evidence for each Class A (measuring and/or sterile), B, C and/or Class D PPE listed including:
      i. Evidence of international registration or compliance to global standards (for imported class B FFP2 masks) i.e. NIOSH, CE certificates
      ii. 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). **(See below for applicable standards)**
         - **Sterile and non-sterile medical (surgical) masks** must be tested according to, and be certified against, the SANS 1866-1:2018 "Medical Devices Part 1: Medical Face Masks" or equivalent international standards, as well as the Legal Metrology Act, 2014 (Act 9 of 2014), in terms of packaging and labelling.
         - **Manufacturers, importers and distributors of Class B respirator masks** must be tested according to, and be certified against the SANS 1866-2:2018 "Medical devices Part 2: Medical Respirators" and the SANS50149:2003 for Respiratory Protective Devices, as well as the Legal Metrology Act, 2014 (Act 9 of 2014), in terms of packaging and labelling.
      iii. NRCS sales permits and homologation certificates showing compliance to relevant compulsory specifications for Class B FFP2 masks
      iv. Evidence of ISO13485:2016 certification of the original manufacturer for each listed PPE (if imported)
      v. Copy of Instructions for Use (IFU) for each listed PPE
      vi. Copy of labelling and packaging of each listed PPE

Amended Licensing and Regulatory Requirements during Covid-19

8. Medical device establishments that hold a valid licence issued in terms of Section 22C(1)(b) of the Medicines Act may not manufacture, import, export or distribute medical devices that have not been

specified in terms of Regulation 5(1)(d) of the Regulations relating to Medical Devices and IVDs on their licence application.

9. Medical device establishments that hold a valid licence issued in terms of Section 22C(1)(b) and authorised to manufacture, import, export or distribute Class A, B, C and/or Class D medical devices must apply for an amendment to such licence and update the product listing to include any mask (classified either as Class A or B medical devices) to be manufactured, imported, exported or distributed.
10. The notification process as defined in the communication to stakeholder "Amendment of Device Establishment Licence" [1] for the amendment of a medical device establishment licence issued in terms of Section 22C(1)(b) of the Medicines Act may not be used for Class A or B masks.
11. The documents required for the licence application are as stated in paragraph (6).
12. Due to the development and capacity constraints of the current accredited laboratories to conduct the fluid resistance test and the splash resistance (blood splatter) test specified in SANS 1866-1:2018 and SANS 1866-2:2018, the SAHPRA may declare conditional exclusions of and modifications to the tests specified in the standards for South African manufacturers.
13. Where the Fluid Resistance test has not been conducted by a verified international lab but all other local tests pass, recommendation is of mandatory visor usage to protect against respirator fluid exposure.
14. **For local manufacturers** during the Covid-19 pandemic period, quality certification to the following tests will be regarded as evidence and compliance to the minimum specifications and requirements for **Class A medical (surgical) 3-ply masks**:
    a. Particulate filter penetration (PFP) test with the minimum testing requirement being to NaCl filtration (sodium chloride) with a limit of 26 % and where possible to paraffin oil and latex particle.
    b. Breathability/ Differential Pressure test
    c. Water adsorption rate – indicator of fluid permeability and imperviousness)
    d. Flammability testing

Note: The required testing above is a combination of SANS1866-1: 2008 and SANS1866-1:2018 to ensure the quality of the masks. This is considered the minimum specification any 3-ply mask must meet to be distributed.

15. **For local manufacturers** during the Covid-19 pandemic period, quality certification to the following tests will be regarded as evidence and compliance to the minimum specifications and requirements for **Class B respirators**:
    a. Particulate filter penetration (PFP) test with the minimum testing requirement being to NaCl filtration (sodium chloride) and where possible to paraffin oil and latex particle.
    b. Flow resistance test - Inhalation resistance at a minimum, but preferably Inhalation and Exhalation resistance (latter mandatory for valved respirators)

[1] https://www.sahpra.org.za/wp-content/uploads/2020/01/Communication-to-industry_licence_amendment_nov2019.pdf

c. Total inward leakage (laboratory)
d. Qualitative facepiece fit test (applicable to FFP2 masks only)
e. Flammability testing

Note: The required testing above is a combination of SANS50149:2003 and SANS1866-2:2018 to ensure the quality of the respirators. This is considered the minimum specification any respirator must meet to be distributed. Specifically, respirators that comply with SANS 1866-2:2018 that do not pass the total inward leakage standard under SANS 50149:2003 will be considered non-compliant.

Additional conditions of the Licence in response to the proliferation of substandard masks

16. The additional licence specific conditions, made in terms of Regulation 5(4), will be listed in Section 11 of the Medical Device Licence to Manufacture and Section 8 of the Medical Device Licence to Distribute.
17. The SAHPRA licence holder must, as specified in regulation 17 of the Regulations relating to medical devices and IVDs and in accordance with the "***8.04 Recall, Adverse Event and Post-Marketing Vigilance Reporting of Medical Devices and IVDs":***
    a. report any adverse event or product quality incidents with the masks to the Authority, and
    b. conduct post-marketing vigilance and monitoring of the quality of the masks.

    Note: Post-market surveillance is the process for manufacturers and distributors of medical devices to collect and analyse experience gained from the medical devices that have been placed on the market. Post-market surveillance is a crucial tool to ensure that medical devices that have been placed on the market remain safe and effective and to consider necessary actions if the risk of continuing to use the device outweighs the benefit.

18. All SAHPRA licensed medical device distributors of Class B FFP2 respirator masks must, prior to distribution and release of consignment, perform initial testing of masks, using South African accredited laboratories, authorised to conduct testing to ensure the masks meet the test specifications as per paragraph (15) above.
19. All SAHPRA licensed medical device manufacturers or distributors of Class B FFP2 respirator masks must, prior to distribution and release of consignment, additionally perform lot to lot testing of masks, using South African accredited laboratories, authorised to conduct testing to ensure that the masks meet the **Particulate Filter Penetration** test (sodium chloride) as sspecified in SANS1866:2 (2018).
22. The final result of the above testing should be reported to SAHPRA as a quality incident as per paragraph (17).
23. These conditions will be requirements from the date of publication of this notice.

DR B SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER OF SAHPRA

DATE: 08 SEPTEMBER 2020