

NATIONAL



AUTHORITY

28<sup>th</sup> October 2021

2455/ID/NDA/10/2021

**Attention:** Manufacturers and Importers

**CIRCULAR NO. 006/DIE/2021**

**RE: LABELLING REQUIREMENTS FOR MEDICAL FACE MASKS**

National Drug Authority has noted with concern the failure to meet the labelling requirements for medical/surgical face masks and surgical respirators which poses a risk to the health workers in the wake of the COVID-19 pandemic.

Medical/Surgical masks intended for medical purposes cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks have to meet certain fluid barrier protection standards and flammability requirements and are also tested for particulate and bacterial filtration efficiencies and biocompatibility. Medical face masks protect both the health worker and the patient.

The labelling of medical face masks shall include but not limited to the following information;

- 1) Name and address of the manufacturer/packer/distributor
- 2) Name/Brand of the product including the term "Medical Mask"
- 3) Lot/Batch identification number
- 4) Type of medical face mask- Type I, Type II and Type IIR
- 5) Type of material/fabric used
- 6) Date of manufacture and Expiry date by month and year
- 7) Manufacturer's Instructions for Use
- 8) Recommended storage conditions
- 9) Precautions to include warnings like "for single use" and "dispose after use".

National Drug Authority further requires compliance to the labelling requirements for surgical instruments and appliances as per Statutory Instrument No. 29; National Drug Policy and Authority (Registration) Regulations, 2014.

Therefore, any consignments of medical face masks imported into the country or manufactured locally without fulfilling the above stated requirements will not be authorized effective 31<sup>st</sup> January 2022.

  
David Nahamya  
**SECRETARY TO THE AUTHORITY**



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**OUR MISSION**

Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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