



የኢትዮጵያ የምግብና መድኃኒት ባለስልጣን

Temporary COVID-19 Medical Product Approval and Import Permit Authorization Directive

April, 2020

Addis Ababa, Ethiopia

Introduction

WHEREAS, it is necessary to prevent and take precautionary measures before greater scale of public health damage due to corona virus which is announced as a pandemic by the WHO and spreading all over the world including Ethiopia;

WHEREAS, it is necessary to issue expedited authorization for manufacture, import or sale of medical products to deal with the existing significant risk of COVID-19;

WHEREAS, it is necessary to provide a clear guidance to manufacturers and importers to organize and submit the required scientific documented evidence in a timely manner for the sale or importation of medical devices that are manufactured, sold or represented for use in relation to COVID-19;

WHEREAS, it is necessary to protect the public from unsafe and poor quality medical products which can increase risk of spread of infectious agents;

WHEREAS, it is necessary to take appropriate administrative measures against violations of this directive and other relevant laws;

WHEREAS, it is necessary to ensure that medical products that are integral to the diagnosis, protection or prevention of COVID-19 can be quickly authorized for sale or importation in order to address the urgent public health need;

NOW, THEREFORE, this directive is issued in accordance with Article 71 (2) of the Food and Medicine Administration Proclamation No 1112/2019.

Part One

General

1. Short title

This directive may be cited as “Temporary Covid-19 medical product conditional approval and import permit authorization Directive No. 50/2020”

2. Definitions

Without prejudice to the definitions provided under the Proclamation No. 1112/2019, in this temporary directive unless the context requires otherwise:

- 1) “COVID-19 medical products” means a medical product that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome corona virus 2 (SARS-CoV-2).
- 2) “Surgical mask” means a disposable medical device that creates a physical barrier between the mouth and nose of the wearer and satisfy the minimum breathability and filtration efficiency as prescribed in this directive.
- 3) “N95 respirator” means a respiratory protective device designed to achieve a very close facial fit and that meet minimum filtration efficiency as prescribed in this directive.
- 4) “Foreign regulatory authority” means a government agency or other entity outside Ethiopia that has a legal right to control the manufacturing, use or sale of medical products within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements.
- 5) “Test kit” means an in vitro diagnostic device that consists of reagents or articles, or any combination of these and that is intended to be used to conduct a specific test.
- 6) “Applicant” means a person who officially requests the authority to manufacture, import, distribute or sale COVID-19 protection and testing medical products.
- 7) “Authority” means the Ethiopian Food and Drug Authority.
- 8) “Proclamation” means Food and Medicine Administration Proclamation No. 1112/2019.
- 9) Any expression in the masculine gender shall also apply to the feminine gender.

3. Scope

This directive shall be applicable on COVID-19 medical products intended to be manufactured locally or imported from abroad.

Part Two

Application for temporary certificate, sale or importation of COVID-19 medical products

4. General

- 1) Any manufacturer, importer, or government and non-governmental organizations required to submit an application to the Authority for the purpose of obtaining temporary authorization certificate to manufacture, import or sell a COVID-19 protection or testing medical product.
- 2) Temporary or regular competence certificate is a pre-requisite to manufacture, import, sale or distribute COVID-19 protection or testing medical product and to obtain Emergency Use Authorization or importation of COVID-19 protection or testing medical product.
- 3) Without prejudice to sub-article (2) of this article, any governmental, non-governmental and private organization engaged in non-medical service or business are eligible to import medical masks and alcohol based hand sanitizers in a quantity sufficient to their staffs or Health facilities in response for COVID-19. such request shall be officially requested by top manager or director of the organization along with free sale certificate or equivalent document and with a commitment not to sale or distribute the products to the third parties other than the staff of the organization.
- 4) In order to obtain temporary approval or import permit authorization, medical products manufactured, imported, sold or represented for use in relation to prevention and testing of COVID-19 shall contain sufficient scientific information and material requested by the Authority.
- 5) Any applicant or organization(s) who intends to donate COVID-19 medical products shall submit supporting letter from MoH-Ethiopia or Regional Health Bureau and free sale certificate from the country of origin or equivalent evidence indicating that products are freely used at the country of origin;
- 6) The application and necessary information shall be submitted electronically through

electronic regulatory information system of the Authority available on website at <https://www.eris.efda.gov.et/> using user name and password provided by the Authority to the responsible person.

- 7) Official application shall be submitted to obtain user name and password that enable the responsible person to submit application request online, and track the application status through the Authority website;
- 8) Authorization for the importation or sale of the COVID-19 medical products prescribed under this Directive shall be granted only if the minimum requirements described in this directive are met.
- 9) If the applicant has questions specific to the type of quality, safety and effectiveness information, they are urged to contact the Medicine Registration and Licensing Directorate, using the following email address: etcovid19@efda.gov.et
- 10) The Authority may request an applicant that has submitted an application for the issuance of temporary approval certificate or permit for importation or sale of a COVID-19 medical product to submit any additional information or any material, including samples that it deems necessary.
- 11) Each consignment or shipment of a COVID-19 related medical product that is imported into Ethiopia shall be accompanied by a copy of the import permit authorization certificate generated from electronic regulatory information and presented at the port of entry to obtain import permit.
- 12) Imported or locally Manufactured COVID-19 medical product shall obtain approval from EFDA prior to selling or distributing such products to the users.
- 13) Only Authorized COVID-19 Diagnostic tests shall be used in Laboratories Designated by Ethiopian Public Health institutes.
- 14) Any applicant who is authorized to manufacture, import or sale a COVID-19 related medical product shall report the incident to the Authority and specify the nature of the incident and the circumstances surrounding the product.

Part Three
Documentation

5. Quality, safety and effectiveness information

- 1) An applicant shall provide documented scientific information including, but not limited to the following in relation to the quality, safety and effectiveness of the Medical product claimed to be used for COVID 19 response:
 - a) A clear description of the medical product, including how it works, any accessories to be used with it, and diagrams/photos of the medical products (if applicable);
 - b) A copy CE certificate or FDA approval or WHO prequalification evidence for COVID -19 diagnostic test kits. If such kits are assembled locally, an applicant shall provide evidence of quality certificate for the raw materials sourced from abroad in addition to the summary of stability study data for on hold time and transportation as well as packaging validation testing. Such manufacturers shall provide Confirmatory test result for final product from any of WHO listed reference laboratories for COVID-19.
- 2) Documented procedures shall be in place with respect of distribution records, complaint handling, incident reporting and recalls of COVID-19 medical products;
- 3) An applicant shall provide a description of the materials used in the manufacture and packaging of the COVID-19 Medical products;

6. Labelling and use instruction

- 1) An applicant shall upload a copy of the label of the COVID-19 related medical product during submission of an application.
- 2) An applicant shall not import, distribute or sell a COVID-19 related medical product unless the product has a label that sets out the following information:
 - a) the name of the medical product;
 - b) the name and address of the manufacturer;
 - c) An identifier of the medical product, including an identifier of any medical device that is part of a system, diagnostic test kit and medical device group;
 - d) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the medical product, such as the size, net weight, length, volume or number of units;

- e) an indication that the device is sterile if the manufacturer intends the device to be sold in a sterile condition;
 - f) the expiry date of the medical product that is determined by the manufacturer on the basis of the stability study data as applicable;
 - g) the directions for use, unless directions are not required, for the device to be used safely and effectively;
 - h) any special storage conditions and handling applicable to the medical products; and
 - i) any safety precautions and warnings.
- 3) The label shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.
- 4) where a package that contains a COVID-19 medical product is too small to display all the information prescribed under sub-article (2) of this article, labelling information need to be displayed on the outside of the package with the exception of the name of the device, unique identifier (Lot or batch Number) and Expiry date.
- 5) Any medical products intended to be used in response to COVID-19 shall fulfil the minimum requirement(s) prescribed in table one (1) of this directive.

Table 1-Technical description and specifications of COVID19 medical products

Item	Technical description and specifications	Reference Standard
Alcohol-based hand rub solution	Health facility Alcohol based hand rub preparation operating procedure approved by MOH-Ethiopia Hand rub formulations containing 75% iso-propanol or 80% ethanol.	As per the specification
Apron	Polyester with PVC coating or 100% PVC or 100% rubber. Waterproof. Minimum basis weight: 250g/m ² . Adjustable neck strap (reusable).	As per the specification
Disinfectant for surfaces hypochlorite solution	Sodium Dichloroisocyanurate (NaDCC), granules, 1kg, 65 to 70% + dosage spoon	As per the specification
0.05% (regular cleaning) or 0.5% (disinfection of spill)		
Face shields	Made of clear plastic and provides good visibility to both the wearer and the patient, Adjustable and to attach firmly around the head and fit snugly	As per the spec

	against the forehead, Fog resistant	
Gloves, non-sterile	powder-free Freedom from Hole	ASTM D3578-05:2015
Gloves, sterile	surgical, powder-free, single use. Freedom from hole and Sterility test should be included as one parameter.	ASTM D3578-05:2015
Goggles	Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure, Enclose eyes and the surrounding areas, Accommodate wearers with prescription glasses, Clear plastic lens with fog and scratch resistant treatments, Adjustable band to secure firmly so as not to become loose during clinical activity, Indirect venting to avoid fogging, May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.	
	Single use, fluid resistant, disposable, length mid-calf to cover the top of	

Cover all Gown	<p>the boots, light colours preferable to better detect possible contamination, thumb/finger loops or elastic cuff to anchor sleeves in place.</p> <p>Option 1: fluid penetration resistant</p> <p>Option 2: blood borne pathogens penetration resistant</p>	<p>EN 13795 high performance or equivalent</p>
Shoe Cover	<p>Made from 25-40 g/m² Medical Grade PP, Non-woven, Water and dust proof ,disposable, Non-skidding soles</p>	<p>As per the spec</p>
Surgical mask	<p>Breathability not greater than 5mmHg</p> <p>filtration efficiency not less than 95%</p>	<p>EN 14683 annex C, or equivalent</p>
Respirator (N95 / FFP2)	<p>Breathability not greater than 5mmHg</p> <p>filtration efficiency not less than 95% ,</p> <p>Good design that does not collapse against the mouth (e.g. duckbill, cup shaped</p>	<p>US NIOSH, or "FFP2" or equivalent</p>

Surgical N95 Respirator	In addition, for N95 respirator sterility test is required	ISO11737-1
<p>Diagnostic Equipment</p> <ul style="list-style-type: none"> • Lab screening test kit • Lab confirmation test kit • RT-PCR kit • Extraction kit • Cartridges for RT-PCR automatic systems • Swab and Viral transport medium • And other diagnostics for COVID-19 	WHO recommended evidence of use in the country of origin and approval by the Regulatory Authority of the country of origin.	
	N.B. the list of Diagnostic items will be updated based on the future health sector need, but the above requirements are applicable as required.	
<p>Clinical Care equipment</p> <ul style="list-style-type: none"> • Pulse oximeter 	CE certificate or US FDA approval or WHO prequalification or emergency use Authorization(evidence of use)	

<ul style="list-style-type: none">• Concentrator O2, 10L, 230V, 50 Hz + acc.• Nasal oxygen cannula, with prongs,• Ventilator patient, for adult, pediatric w/acc.• IR Thermometer• CPAP, with tubing and patient interfaces for adult and pediatric, w/acc.• Suction pump, mechanical• High-flow nasal cannula (HFNC) w/acc• And other clinical care equipment	<p>N.B. the list of Diagnostic items will be updated based on the future health sector need, but the above requirements are applicable as required.</p>	
---	---	--

Part Four
Miscellaneous

7. Administrative Measure

- 1) Any COVID-19 related medical product which violates the requirements of this directive may be, as appropriate, seized, confiscated, disposed or returned to its country of origin at the owners cost as per Art. 65(5) of the Proclamation.
- 2) Without prejudice to Sub-Article (1) of this Article, due to the nature of the application and issuance of expedited authorization to deal with the significant public health risk of COVID-19, the Authority may cancel the conditional approval, import permit authorization for importation or sale under the following conditions:
 - a) When the Authority determines that the benefits no longer outweigh the risks of the medical products and that the health or safety of Ethiopian patients, users or any other person may be unduly affected;
 - b) When the Authority determines that the terms and conditions imposed are not met; or
 - c) The authorization for sale of a COVID-19 medical product that has been issued by a foreign regulatory authority is suspended or cancelled.

8. Service fee

Any person who seeks temporary approval certificate under this directive may be required to pay applicable service fees to the Authority in accordance with Service Fee Regulation No. 370/2018.

9. Inapplicable laws

Any working procedure or customary practice which is inconsistent with this directive shall not be applicable with respect to those matters provided under in this directive.

10. Effective date

- 1) This directive shall enter into force on 10/04/2020.
- 2) Notwithstanding sub-article (1) of this Article, this Directive shall remain in effect until control of the COVID-19 Pandemic and further notice by the government.

Heran Gerba
Director General
Ethiopian Food and Drug Authority