Ethiopian Food and Drug Authority

Guideline for Registration and Import Permit of Medical Device Accessories and Spare Parts

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Table of Contents

ACRONYMS

EFDA	Ethiopian Food and Drugs Administration
ISO	International Standards Organization
USB	Universal Serial Bus
eRIS	Electronic Regulatory Information System
NGO	Non-governmental Organization
MA	Market Authorization
GMP	Good Manufacturing Practice
CE	European Conformity
USFDA	U.S. Food and Drug Administration
CAPA	Corrective Action and Preventive Action
EU	European Union
NB	Notified Body
SUD	Single Use Device
TGA	Therapeutic Goods Administration – Australia
IRB	Institutional Review Board
IMDRF	International Medical Device Regulators Forum

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- Keneni Benti (MSc in Biomedical Engineering), Medical Device Registration Dossier Assessor at EFDA
- Selamawit Asfaw (Chief Biomedical Engineer), Medical Device Registration Dossier Assessor at EFDA
- Solomon Shiferaw (Senior Pharmacist), Technical Advisor, EFDA

OVERALL SUMMARY OF THIS GUIDELINE

Items type: Accessories and Spare parts

Regulation scope: Marketing Authorization certificate issuance and Import permit

Establishments to be given permission: Importers of parent devices, importers of these items, maintenance centers, manufacturers, healthcare facilities, NGOs, etc.

Importation of unregistered Accessories and Components by:

- Medical device importer of the same parent device from the manufacturer other than parent device manufacturer.
- Accessories and components importer from the manufacturer other than parent device manufacturer.
- Healthcare facilities importation permit from the manufacturer other than parent device manufacturer.
- Medical Equipment Maintenance center importation permits from the manufacturer other than parent device manufacturer.

1 INTRODUCTION

The Food and Medicine Administration Proclamation (Proclamation No. 1112/2019) states that medical devices shall be registered and granted marketing authorization before being made available for public use. The registration process requires assessment of quality, safety and performance of the medical device. Furthermore, the rigor of regulatory assessment of medical device shall be commensurate with the device type, nature, and potential risk to human health.

Medical device refers to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, that is:-

a) recognized in a pharmacopoeia or any supplement to it;
b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in human being or;
c) intended to affect the structure or any function of the body of a human being and which does not achieve any of its principal intended purposes through chemical action within the body of a human being and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

All articles, including accessories, that meet the definition of "medical device" above are regulated under article 2(22) of the Authority's Proclamation No: 1112/2019.

Through this guideline, EFDA would like to give clear guidance for applicants to submit relevant supporting documents for registration and importation permit of medical device accessories and spare parts. In addition, this guideline explains the type of devices that are considered as an "accessory" and "spare part" and describes the processes to allow requests and pathways for issuance of marketing authorization certificate and one time import permit of these accessories and spare parts as per the requirements set in this guideline.

This information is expected to provide a greater level of transparency with regards to the regulatory requirements of accessories and spare parts and will aid the Authority's staff and industry in assuring that the medical devices are subject to the appropriate level of regulatory oversight by EFDA.

2 SCOPE

This guideline is applicable for marketing authorization and one time importation permit of medical device accessories and spare parts which are to be imported or locally manufactured.

This guideline is not applicable for accessories that are registered as a part of the parent medical devices.

3 PURPOSE

The purpose of this guideline is to provide guidance for applicant on marketing authorization registration and import permit medical devices accessories and spare parts.

4 DEFINITIONS

Accessory: - A finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices. Accessories are designed specifically for a device, and may include consumables, parts, add-ons, and other components for use in conjunction with, or for upgrade, replacement and repair of parts of a medical device.

Component: - Any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

Spare part:- Is a part for replacement of existing components of a device, the conformity of which has already been established.

Finished Device: - Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Parent Device: - A finished device whose performance is supported, supplemented, and/or augmented by one or more accessories.

5 GENERAL PRINCIPLES

Accessories or Components (parts) which are together with the parent devices during the device's premarket registration application can be applied as a "*system*" together with the parent devices. EFDA has a guideline on '*how to group medical device and its accessories and components for registration application purpose as a "system" so as to make one application'*.

EFDA intends to determine the risk of accessories and spare parts and the regulatory controls necessary to provide a reasonable assurance of their safety and effectiveness according to their intended use.

Because accessories are intended to be used with and to support, supplement, and/or augment one or more parent devices and spare parts intended to replace component(s) of a parent device, EFDA intends to determine the risks of accessories and spare parts when used, as intended, with the parent device type.

Determining the risks of accessories and spare parts according to their use with parent devices does not mean that all risks of a parent device are imputed to the accessory or spare part; the risk profile of an accessory or spare part can differ significantly from that of the parent device, warranting differences in regulatory classification. In determining the classification of an accessory or spare part, EFDA intends to evaluate the risks imposed by the accessory's or spare part's impact on the parent device and any unique risks of the accessory independent of its parent device.

As with the classification of any other device, the types of regulatory controls necessary to control these risks of the use of the accessory and spare part with the parent device will determine the regulatory control for accessories and spare parts.

Accessories and spare parts need to be given independent risk- and regulatory control-based classification to that of the parent devices. These accessories and spare parts class can be the same or lower than that of the device(s) with which they are intended to be used.

6 APPROACHES FOR IDENTIFICATION OF MEDICAL DEVICE ACCESSORIES AND SPARE PARTS

The accessory and spare parts classification process begins with the analysis of whether the article under consideration is an accessory or spare part or not. Following identification of the item as accessory or spare part or neither of them, this particular item's impact on the parent device's safety and performance should be assessed. This is because the registration (marketing authorization) and importation permit requirements depend on the significance of the effects that can be caused by the requested accessory or spare part on the parent device's safety and performance. Hence, the manufacturers of the accessories and spare parts are responsible to

determine the risk level of their accessories and spare parts depending on the items impact on the parent medical device's intended use.

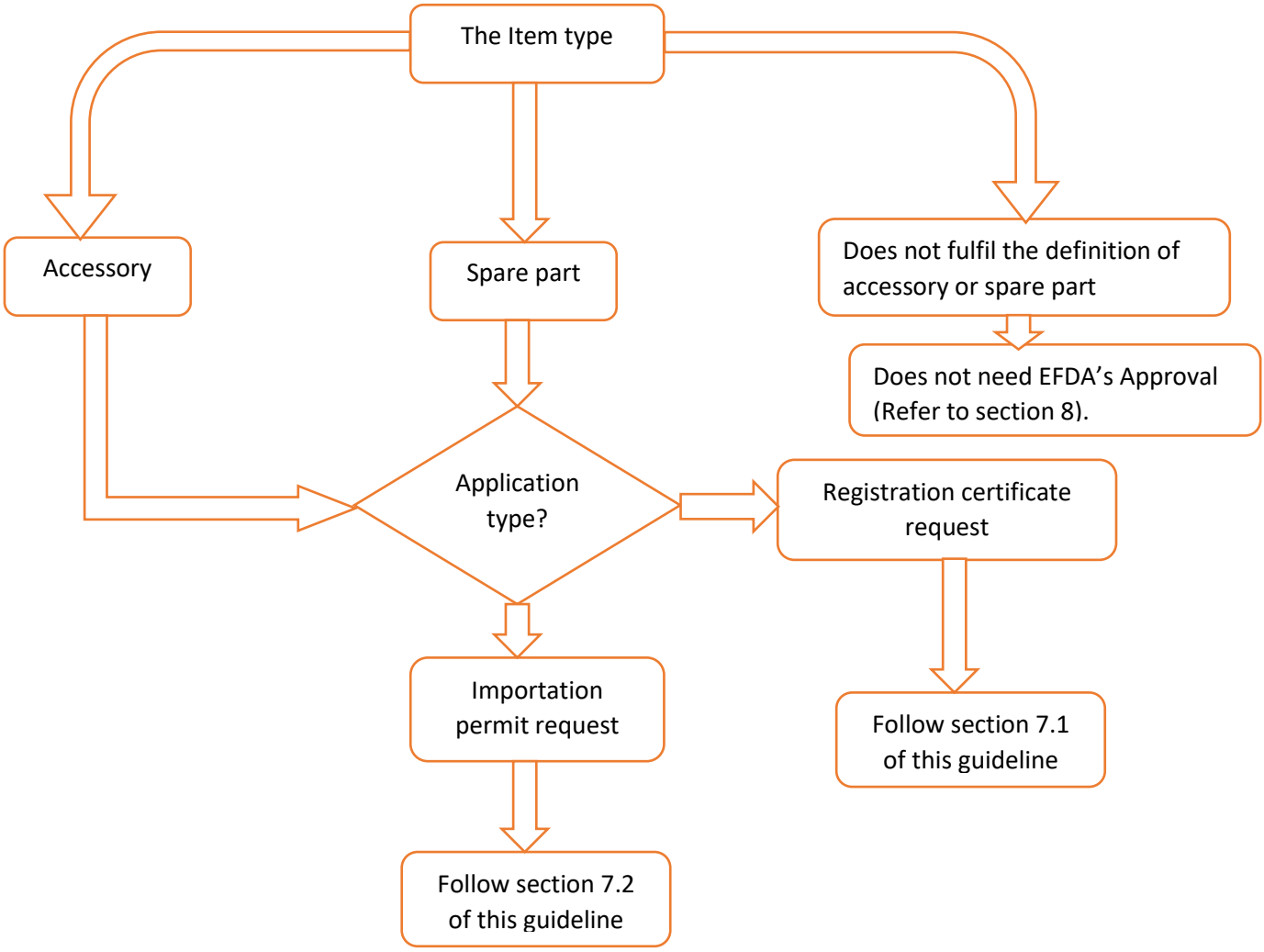

Figure 1: Flowchart for accessory and spare part identification and dossier requirements

7 APPLICATION REQUIREMENTS, EVALUATION AND APPROVAL PROCESSES

There are a number of scenarios to submit and get approval for the request of importation permit or issuance of market authorization certificate for medical device accessories and spare parts. These approaches are divided based on the following concepts:-

- Application submission for issuance of marketing authorization certificate of Medical device accessories or spare parts by an establishment (importer or registrant) who is engaged in the business of medical device and/or medical device accessories and spare parts importation and/or registration.
- Application submission of request for importation permit of unregistered Medical device accessories and spare parts by healthcare facilities, NGOs, Government agencies, licensed medical device installation and maintenance centers.

7.1 Application for Marketing Authorization Certificate

Establishments licensed by EFDA and engaged in Registration and/or importation of medical devices and/or their accessories and spare parts are expected to submit all required applicable documents described under section 7 of this guideline for registering their products. The applicants should get the login details of the Authority's online registration platform from an authorized person to request for issuance of marketing authorization certificate. No person or company can apply for the marketing authorization certificate before being licensed by the Authority to register and/or import such products.

7.1.1 Administrative requirements

- The applicant shall fill the application form online in the eRIS information system
- Cover letter: The license holder/marketing authorization holder should provide an original cover letter (with the company's original stamp and an authorized person's signature from the company) describing that the applicant (local agent) mentioned on the letter is the one authorized to submit the application for registration of the medical device accessories or spare parts described on the letter. The content and format should be as per the template in *Annex III of General Guidelines for Medical device Marketing Authorization* by only replacing device's name by accessory's or spare part's name.

- An agency agreement made between the manufacturer of the medical device accessories or spare parts and the agent responsible for the registration and/or import, distribution, and sale of the product in Ethiopia.
- Copy of market authorization certificate of the parent medical device or if the parent medical device is not registered, evidence that the parent device are available for use in health facility(ies) of Ethiopia.
- Free sale certificate (as applicable). The free sale certificate issued by the competent national regulatory authority, which indicates the name(s) of the medical device accessories (with model if applicable) and explains whether the accessories are freely sold in the country of origin should be provided; if not, the reasons thereof should be clearly stated with appropriate justification.
- Declaration of conformity
- Quality management system confirmatory statement such as CE or ISO certificate (applicable if the manufacture of accessary is not registered previously)
- Evidence of payment for registration as indicated in the fee service regulation of the authority.
- Applicants who need to import medical device accessories and spare parts shall be consistent with the recent Medicine and Medical device import, export and wholesale directive of the Authority

7.1.2 Technical requirements of Accessories and Spare parts

In order to streamline the submission and evaluation of the safety and effectiveness of accessory or spare part, applicant should provide the following technical information:

a) Clear and detail description of the accessory or spare part and its intended use when used with the parent device(s).
b) Device Information and Summary:
    - A description of the relevant parent device(s);
    - Identification of parent product(s) to which the accessory or spare part is compatible, including model number of parent device, connector type, etc.;
    - A description of the ability for the spare part or accessory to be compatible with a specific parent device, multiple parent devices, or a class of devices;

- A description of the technical characteristics of the accessory or spare part, which ensure compatibility with a specific parent device, multiple parent devices, or a class of devices;
- A description of how the accessory supports, supplements and/or augments the performance of the parent device.

c) Classification summary and recommendation:
   - The accessory should be classified as per the guidelines for medical device classification of the Authority.
   - The classification summary should include a rationale for why the accessory or spare part does not fit within any identified classification for the parent device(s);

d) An identification of the risks to health presented by the accessory or spare part and proposed mitigation measures;

e) Summary of the safety and performance data supporting the registration of the accessory or spare part:
   - Reference to all reasonably known relevant data and information, including new information, about the accessory or spare part in combination with the parent device(s);

f) Labeling for the accessory and spare part with adequate instructions for use with the parent device(s): The labeling information should include
   - Name of the accessory or spare part, model/serial number, name and address of manufacturer and manufacturing site,
   - Include labeling instructions to address compatibility of the new accessory device and the parent device(s), including any relevant performance data to support compatibility;
   - Include relevant technical characteristics of the accessory,
   - If the accessory is sterile, such information should be reflected in the labeling information.
   - If the accessory is single use only, such information should be reflected in the labeling information:

7.2 Application for Import Permit of unregistered Accessories and Spare Parts

Establishments such as healthcare facilities, NGOs, government agencies, licensed medical device installation and maintenance centers can request the Authority for importation permit of medical device accessories or spare parts.

Import permit application requirements:-

- Filling all necessary and applicable product's information (of the accessory and spare part) required on eRIS.
- Dated and signed cover letter by the requesting establishment.
- Appropriate Proforma Invoice
- Marketing Authorization certificate or Import permit approval certificate issued for the parent device by EFDA. (Other means of verifying the parent device's approval by EFDA is also acceptable).
- Marketing Authorization certificate or free sale certificate or relevant ISO standard conformance certificate for the requested accessories and spare parts. (Optional).
- Declaration of conformity by the manufacturer of the accessory or spare part under evaluation.

Note

- No medical device accessories or spare parts shall enter in to the country without prior permission of the Authority.
- If the medical device accessories and spare parts are to be supplied by donation, applicant shall follow the recent relevant document(s) of the Authority to understand the applicable requirements.

8 SOME EXAMPLES OF ITEMS WHICH ARE NEITHER ACCESSORY NOR SPARE PART AND THEREFORE DO NOT NEED EFDA'S APPROVAL

An article meets one or more of the following criteria's may not be considered as a medical device accessory or spare part. Applicants of such products should not make any request to the authority for their registration or importation.

1. An Item that does not fulfil the definition of medical device accessory or spare part.
2. If a replacement part or component which can be purchased off-the shelf. Example:
    - Batteries, USB cables and printers, which can be purchased from off-the shelf and not fall in medical device definition.
    - A mobile phone that is used as a general platform for applications that include mobile medical applications that are medical devices, or an off-the-shelf computer monitor used to display medical data would not be considered accessories unless they are intended for use with such devices by the labeling and promotional materials.

9 REFERENCE

1. Definition of Medical Device, Medical Device Guidance Document, Ref. No. MDA/GD/0006, 1st Edition, Medical Device Authority, Ministry of Health, Malaysia, March 2014.
2. Medical Device Accessories-Describing Accessories and Classification Pathways, Guidance for Industry, USFDA, December 2017.
3. Guideline for Registration of Medical devices, 3rd Edition, Food and Drug Authority of Ethiopia, September 2014.