GUIDELINE FOR REGISTRATION OF MEDICAL DEVICES IN SRI LANKA

Cosmetic Devices and Drug Regulatory Authority (CDDA)
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PREFACE

This document is intended to provide general guidance and will assist importers and local manufactures of medical devices in the submission of applications for product registration.

1.0 INTRODUCTION

1.1.PURPOSE

This document is meant to provide general guidance and assist to medical device importers and local manufacturers when submitting applications for regulatory approval to the CDDA.

1.2 BACKGROUND

In Sri Lanka “The Cosmetics Devices and Drug Act No.27 of 1980 and its subsequent amendments are the legislative framework to regulate Cosmetics, Devices and Drugs.

In case of devices registration , individual products are registered separately after evaluating each product for following parameters i.e. quality, safety, effectiveness and durability and will issues a 'marketing authorization', or licence.. For imported medical devices the registration application should be submitted through the local agent representing the manufacturer in Sri Lanka to the CDDA.

Local manufacturing plants are also licensed directly by CDDA. Regarding manufacturing, the main focus is on the certificate of good manufacturing practices issued by the regulatory authority of manufacturing country.

According to the regulations, documents required for registration of medical devices should be submitted conforming to the form A Schedule 1 Regulation 4 (3). [Annex 1]

1.3 SCOPE

This document applies for all medical devices. The government of Sri Lanka (CDDA) regulates the manufacture, sale and importation of devices by requiring that all devices be registered before they can be manufactured, supplied, distributed or sold.

1.4 DEFINITION OF A DEVICE

"Device" means any article, instrument, apparatus or contrivance, including any component, part of accessory thereof;, manufactured or sold for use in,

- the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof, in man or animal,
- restoring, correcting or modifying a body function or the body structure of man or animal,
- the diagnosis of pregnancy in human beings or animals, or
- the care of human beings or animals during pregnancy and at and after birth of the off-spring, including care of the off-spring and includes a contraceptive device but does not include a drug

2.0 REGISTERING PROCEEDURE OF DEVICES

Persons who import or manufacture medical devices or have products imported or manufactured on their behalf are responsible for applying to the Cosmetics, Devices & Drug Regulatory Authority (CDDA) to get pre marketing approval. The applicant shall be responsible for the product and all information supplied in support of his application for registration of the product.

2.1 Responsibilities of a applicant

The applicant/ registration holder either manufacturer or importer must in writing declare that they are responsible for ensuring safety, quality & effectiveness of the registered devices and that the product complies with all existing regulations and specifications (standards)

Responsibilities include

- Responsible for product and all the information supplied in support of his application for registration of product and for updating any information relevant to the product
- having effective procedure for handling any adverse effects that may occur with the product in use.
- Execute suitable quality control
- Ensuring appropriate packaging material is used to guarantee quality of the product

2.2 The procedure of registration of devices is as follows

2.2.1 Applying for a sample licence

In order to apply for the sample license the applicant should submit

- Request letter for registration
- Business registration certificate BR(1)
- Authorization letter issued by the manufacturer by appointing the applicant as the local agent for the relevant products

Authorization letter should be addressed to director CDDA & it should be signed by the General manager or CEO of the manufacturing company with the name & designation. In addition the information regarding other agents in other countries are preferred.

- Copy of free sale certificate

If above documents are in order the applicant will receive payment letter from the receiving point of CDDA & then he should have to make relevant payments to the shroff counter at the Ministry of Health (MOH). Along with the above relevant documents yellow receipt which is issued by MOH should be submitted to the CDDA receiving point after making the date stamped on the receipt.

Then at the receiving point the application will be entered in to a register.

The sample licence will be issued in three copies which is valid for period of one year from the issuing date & applicant will be able to collect it from the receiving point. (Another copy will be attached to the dossier)

Then local agent can submit the dossier with samples.

2.2.2 Submission of application

The application need following requirements on submission

- application should be in a box file
- three separate files are to be prepared
- First page should contain following details
  Eg. approved name, brand name, Manufacturer's details, impoter's details.
- application should be numbered inserting polio numbers from top to bottom & bottom to top as well

(1). Basic requirements

- Index
- Acknowledgement
- Copy of sample import licence
- Schedule I Form A Regulation 4 (3)

I. Name and address of the applicant , manufacturer and importer

II. Name of the Device , brand name (if any), official or approved name

III. A Certificate from the health authorities of the country in which it is produced confirming that the device is in use there and the period of use and if not, reasons for not marketing it in the country of the manufacture (Free sale certificate) - original or copy of a free sale certificate which is attested by a FDA/ Medical device control agency / Sri Lankan embassy or foreign ministry is acceptable original attested by D/ CDDA

IV. List of countries with documents to prove registration status in other countries eg. Foreign country registration certificate

V. Fully packed samples of the devices

The applicant should be able to submit at least two samples from commercial batches in order to send for external evaluators

eg. For sterile products, Single user products

Two samples are also be submitted for instruments & apparatus

In case of machineries & highly expensive devices the local agent should be in a position to demonstrate description of those machines to external evaluators when they require to do so.

(The applications without relevant samples are not be acceptable & will not be sent for external evaluators)

VI. Sample of the label(s) with inner & outer cartons

Product catalogue to aid the identification of the product

Lot no., Manufacture date , Expiry date, manufacturers name address ,country of origin should be indicated on the label

- Schedule I form B Name, designation & signature of the applicant

(2) Other Requirements

The following documents should be submitted in addition to the basic documents / details above mentioned where necessary / if available

1) Test reports should be submitted for the below mentioned products

- Independent analytical certificates from Industrial Technology Institute (ITI) or govt. accreted laboratory in Sri Lanka (original report should be submitted) for products which are directly in contact with the blood stream such as disposable syringes, disposable needles, IV cannulas IV catheters etc. Test reports are to be submitted according to pharmacopeial standards
- Standardization reports from Sri Lanka Standard Institution (SLSI) are needed for certain items

  eg. Plasters, gauze, feeding bottles, sanitary Napkins, bandages, latex condoms, Surgical gloves etc.
- ISO certification in order to access the design, development, manufacturing as well as for post marketing monitoring of safety and performance of the manufacturer.
- CE accreditation in order to prove the free sale within the Europian Union

2) Following requirements should be fullfilled for Absorbable sutures with the application.

- All the samples of absorbable sutures will be kept at the CDDA for six (6) months before sending for evaluation to the relevant consultant.
- Details of the raw material sources, purchasing details should be provided.
- Analytical certificate of the finished product according to relevant standards should be provided from an Independent Laboratory as well as from manufacturer.
- Stability data for entire shelf life of the finished products should be provided.

3) Where necessary certificate of approval from relevant authorities should be provided.

eg: - For radiation emitting devices approval obtained from Atomic energy Authority of Sri Lanka

- Certification from the relevant health authority of the country of manufacturer that the product is free from BSE (Bovine Spongiform Encephalopathy) should be obtained for animal derived products eg: Surgical Catgut

4) Instructions for use should be in three languages English, Sinhala & Tamil for relevant products such as Glucometer, Hearing Aids, Ear and Forehead Thermometers should be submitted whenever necessary.

5) For High cost cardiac devices relevant information according to the "Guidelines for registration of Cardiac devices/ stents" dated 28th Feb 2009 prepared by the committee appointed to overlook the registration of High Cost Cardiac Devices (HCCD) should be submitted. (A copy be to be included in web site)

6) For Borderline devices with therapeutic claims relevant clinical trial data should be submitted.

7) Other special requirements would be considered on case by case basis and as decided by the Medical Device Evaluation Sub Committee (MDESC) of the CDDA.

(3) Labels & Product information leaflets

Labelling requirements

The container of every device imported, manufactured, processed or packed locally or sold or exposed for sale shall have labels bearing the following information clearly.

1) The approved name (official name) & Brand name (Trade name). Where standards are available labels more should be produced accordingly.
   eg: Absorbent Cotton wool BP (British Pharmacopoeia)
2) The intended purpose of use.
3) Any special storage conditions that may be necessary
4) Any warning and precautions that may be necessary
5) The date of manufacturer and date of expiry where applicable; (An indication of the date until which the device may safely be used expressed as the year and the month
   (eg. single –use disposable devices)
6) The batch or lot number assigned by the manufacturer ;
7) The name and address of the manufacturer including country of manufacturing;

8) Adequate directions for use of the device
9) For imported devices, the label to the outer packaging to have the name and address of the local importer
10) Sufficient details for the user to identify the device, or where relevant, the contents of any packing.
11) An indication that the manufacturer for single use has specified the device "For single use only".
12) Date of manufacture & Date of expiry, any special storage and/ or handling conditions on the external packaging condition
13) When a medical device is manufactured by a source other than the principal manufacturer (loan/ contract manufacturer etc.), the label should clearly identify the name and address of such manufacturer as follows. "Manufactured by …… For ……" and the country of origin should be clearly stated in the label.
14) If a particular medical device is distributed by a source other than the principal manufacturer, the label must clearly identify the name and address including the country of origin of the distributor as follows. "Manufactured by ……. Distributed by……".
15) In addition to the above, any other requirements for labeling that may be mandated from time to time by the CDDA shall be complied with.

Product information leaflet

1) The performance intended by the manufacturer and undesirable side- effects.
2) The information needed to verify the device is properly installed and can operate correctly and safely. Replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.
3) Detail of any further treatment or handling needed before the device can be used (Eg. sterilization, final assembly, calibration etc.)where applicable should be indicated.
4) An indication that the device is sterile and also necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re- sterilization. /or whether it cannot be re- sterilized /or cannot be re-used by sterilization
5) If the device is to be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose.

6) If the device is implantable, information regarding any particular risk in connection with its implantation.
7) Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations or treatment
(Eg. Electrical interference from electro – surgical devices or magnetic field interference from magnetic resonance imagers).
8) If the device is reusable, information on the appropriate processes to allow reuse, including, disinfections, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of re-uses.
9) Where device are supplied with the intention that they be sterilized before use, the instruction for cleaning and sterilization should be such that, if correctly followed, the device will "still comply with" the essential principles of safety and performance of medical devices".
10) If the device emits radiation for medical purposes, details of the nature, Type, intensity and distribution of this radiation.
11) The instructions for use should also include, where appropriate, details allowing the medical staff to brief the patient on any contra indications, warnings and any precautions to be taken. These details should cover in particular:
(a) Precautions to be taken in the event of changes is performance of the device.
(b) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, proximity to other devices, etc.
12) Adequate information regarding any medical product or which the device in question is designed to administer, including any limitations in the choice of substances to be delivered.
13) Precautions to be taken against any special, unusual risks related to the disposal of the device.
14) Any medical substances incorporated into the device as an integral part of the device.
15) Degree of accuracy claimed for devices with a measuring function.
16) Any requirement for special facilities, or special training, or particular qualifications of the device

2.3 Multiple applications

(1) Separate application to be submitted when a medical device consists of different constituents/ components. Each and every component of that system is registered separately.

eg: (i) Orthopedic system - separate applications should be produced for bone plates, nails, pins, screws

(ii) Dental appliances

(2) A medical device although the manufacturing process is same and share a common intended purpose is registered separately.

eg: (i) Condoms with different colour, size, texture

(ii) Syringes with different volumes

(iii) CV catheters, haemodialysis instruments, blood bags (for single, double and triple)

(3) In vitro diagnostic devices that consist of reagents or article intended to be used in combination to complete a specific intended purpose is registered as a group

eg: Hematology analyzer with standards, programme and reagents

Or as separately

eg: Blood grouping reagent, blood glucose monitoring system with component

A medical device although the manufacturing process and share

(4) A medical device consisting a collection of devices and has a common intended purpose is registered as a group.

eg: (i) Electro surgical unit with standard accessories (electrodes, electrode holders, leads, Plates, plug adopter)

(ii) Centrifuge and standard accessories

(iii) Nebualizer system

2.4. File submission procedure

- Application should be submitted to the pharmacist at the receiving point and he will issue processing fees payment letter & applicant have to make the payments to the shroff counter of the ministry of health. From the shroff counter yellow receipt will be issued and it should be attached to the dossier after making date stamped.

- Complete application should be submitted to the pharmacist at the receiving point with samples where the dossier will be cross checked with a checklist by the pharmacist & will decide whether the dossier is in order.

- Pharmacist will enter the dossier into a register with a serial no. (DVR no). & the acknowledgement will be given back to the local agent with DVR no., signature & date stamp.

Local agent can follow up on dossier with the DVR no. hereafter.

Special Requirements

Special requirements, which apply only to some medical devices,

- Chemical, physical and biological properties of the medical device
- Minimization of risk of infection and microbial contamination to a patient, a user or any other person
- Construction and environmental properties of the device should be safe
- Medical devices with a measuring function should provide accurate precise and stable measurements
- Protection against radiation of the patient user or any other person
- Medical devices connected to or equipped with an energy source must be designed and produced in such a way that it ensures the performance, reliability and repeatability of the system and risks associated with a single faulty condition are minimized.

2.5. Processing of evaluation

Applications are subjected to basic evaluations by the internal evaluators. According to basic evaluation if dossier is unsatisfactory those applications will be rejected. If the application is in order, the name will be sent to external evaluators with samples for clinical evaluation.

With the external evaluators report the application will be submitted to MDESC for discussion & to get the decision. According to the committee's recommendation & approval the application will be granted provisional/full registration. If the application is failed with in the process the local agent can appeal for the registration.

2.5.1 Validity of registration

- Full registration

Full registration of devices will be valid for a period of five (5) years and is specified in the certificate. Renewal of registration is to be done every five yearly.

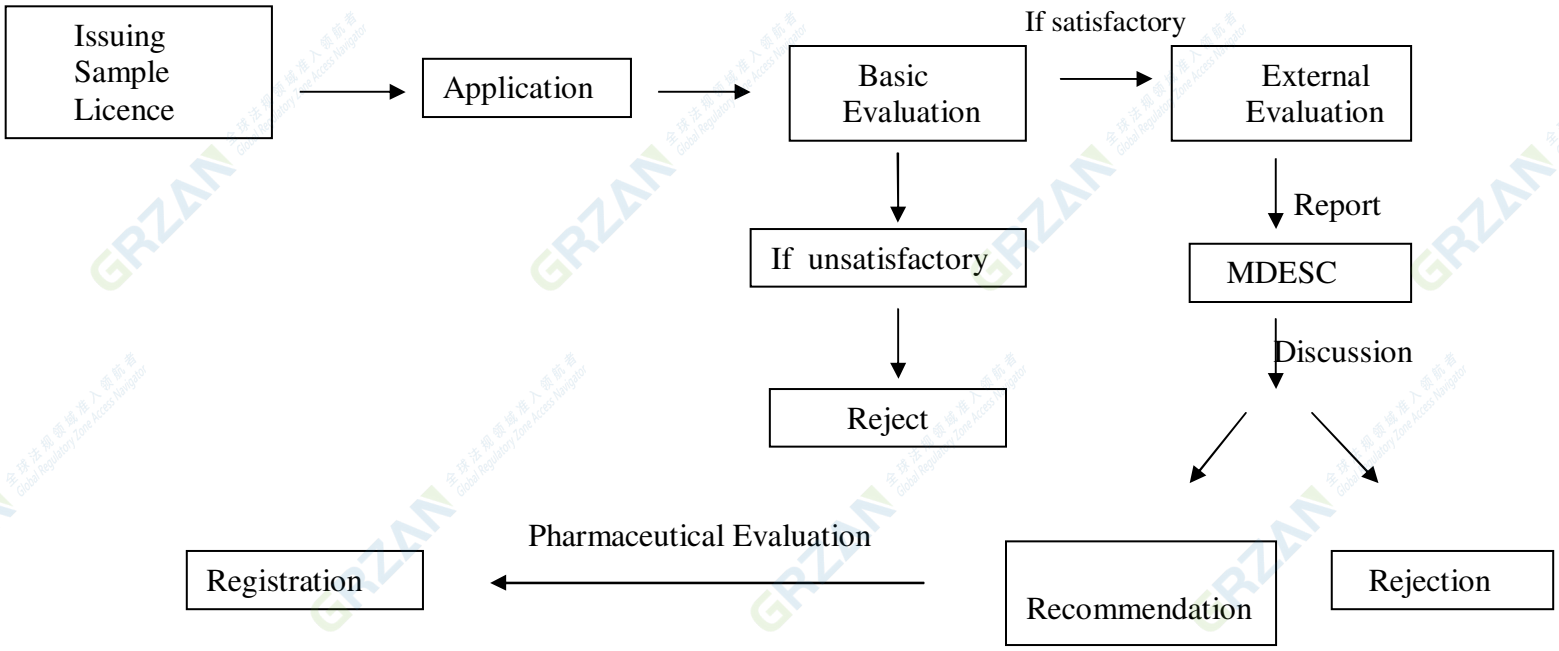
- Provisional Registration

Under certain circumstances provisional registration will be granted for a period of one year such as ;

- New device
- New specifications of a device
- New manufacturer
- In case of agency transfers
- Products which have been suspended due to quality problems
- Applications that do not provide required documentation as outlined above for registration of a devices

These registration certificates will be issued by the CDDA in three copies. One copy will be given to local agent, another copy will be attached to dossier & other copy will be filed in a CDDA

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2.5 Applying for import licence

- After applicant has obtained a registration, with the copy of registration certificate & request letter the applicant can apply for import licence.
- The payment should be made into shroff counter of the MOH and yellow receipt should be submitted after making date stamp with the above documents to the receiving point of the CDDA. The import licence will be issued in three copies. One copy will be issued to applicant , another copy will be attached to the application and other copy will be filed in CDDA.
- Import licence should be renewed every year