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Overview on Regulatory Requirements for Medical Devices in Srilanka - National Medicines Regulatory Authority/NMRA

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

In the health-care industry, medical devices are becoming increasingly significant. One of the most challenging aspects of developing and manufacturing medical devices is keeping up with regulatory regulations and incorporating them into the process Registration, licensing, manufacture, importation, and all other elements of medical devices shall be regulated and controlled by the National Medicines Regulatory Authority in accordance with the National Medicines Policy. In this article we discuss about regulatory overview and registration of medical devices in Sri Lanka. A "medical device," as defined by the Act, is any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, that is used in or on humans for the purposes of: Diagnosis, prevention, monitoring, treatment, or alleviation of disease; Anatomy or physiological process investigation, replacement, or alteration, Conception control. Any change in product information should be reported to the NMRA as soon as possible during the evaluation

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process and after product registration, especially if it involves rejection/withdrawal, additional data on product quality, effectiveness, or safety, or the manufacturers' current Good Manufacturing Practice (cGMP) compliance. The sample license will be produced in three copies, each of which will be valid for one year from the date of issue, and will be available for pick-up at the reception point. (An extra copy of the dossier will be included).

Keywords: Medical devices; Srilanka; registration; national medicines regulatory authority (NMRA); medical device evaluation committee (MDEC).

1. INTRODUCTION

1.1 Regulatory Overview

According to the National Medicines Regulatory Authority Act No. 05 of 2015 the National Medicines Regulatory Authority shall be responsible for the regulation and control of registration, licensing, manufacture, importation and all other aspects pertaining to medical devices in a manner compatible with the National Medicines Policy; [1]

1.2 Definition of a Medical Device

As defined in the Act a “medical device” means any instrument, apparatus, appliance, software, material or any other article, whether used single or in combination, including the software necessary for its proper application intended by the manufacturer used in or on human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception;

and which, while not achieving its intended action in or on the human body through pharmacological, immunological, or metabolic mechanisms, could be helped in its function by such means; Ayurveda or Homeopathy devices are not considered medical devices.

Any change in product information should be reported to the NMRA as soon as possible during the evaluation process and after product registration, especially if it involves rejection/withdrawal, additional data on product quality, effectiveness, or safety, or the manufacturers' current Good Manufacturing Practice (cGMP) compliance. The sample license will be produced in three copies, each of which will be valid for one year from the date of issue, and will be available for pick-up at the reception point. (An extra copy of the dossier will be included [2].

2. DISCUSSION

2.1 The NMRA's Role and Responsibilities in the Approval of Medical Devices

The National Medicines Regulatory Authority (NMRA) is responsible for ensuring that medical devices available in Sri Lanka are of acceptable quality, safety, and suitability for their intended use. As a result, any medical devices that fall under the aforementioned definition should be registered with the Authority and a license obtained before they can be manufactured, imported, repackaged, sold, distributed, or offered for sale in Sri Lanka.

All foreign medical device manufacturers should apply for registration through a Marketing Authorization Holder (local agent) in Sri Lanka, who will be responsible for all aspects of the medical device's registration, licensing, importation, sale, and distribution in Sri Lanka, as well as handling quality failures [3].

2.2 Medical Device Evaluation Committee (MDEC)

The Medical Device Evaluation Committee (MDEC) formed under NMRA Act carries out technical evaluation of the medical devices forwarded for registration by considering the quality, safety, effectiveness, need and cost of such devices. The Medical Device Evaluation Committee (MDEC) is a group of experts from diverse medical and pharmaceutical disciplines who meet monthly to decide on applications for

marketing authorization of medications and to make policy decisions related to marketing authorization [4].

2.3 Registration of Medical Device in Sri Lanka

Persons who import or manufacture medical devices, or who have items imported or made on their behalf, must request for premarketing authorisation from the Cosmetics, Devices, and Drug Regulatory Authority (CDDA). The applicant is responsible for the product as well as the information provided in support of his product registration application [5].

2.4 Responsibility of the Marketing Authorization Holder [5]

- The applicant is responsible for the product and any information provided in support of his application for product registration.
- Six months before the certificate of registration expires, the applicant must submit supplementary documents for renewal.
- The holder of a marketing authorization is responsible for the quality, safety, and efficacy of his products.
- applicant should be responsible for updating any information relevant to the product/ application. The NMRA should be informed in a timely manner any change in product information during the course of evaluation, and after product registration, especially if the information pertaining to rejection/ withdrawal, additional data on product quality, effectiveness and safety or current Good Manufacturing Practice (cGMP) compliance of the manufacturers

2.5 The Procedure of Registration of Devices is as Follows

➢ **Applying for a sample licence**

The applicant must provide the following documents to apply for the sample licence:

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

The letter of authorization should be addressed to Director Cosmetic, Device and Drug regulatory authority (CDDA) and signed by the General Manager or CEO of the manufacturing company, along with their name and designation. Furthermore, information on other agents from other countries is preferred.

- **Copy of free sale certificate**

The applicant will receive a payment letter from the receiving point if the above documents are in order.

He should then have to pay the appropriate fees to the Ministry of Health's Shroff counter (MOH). Along with the above-mentioned documents, the MOH's yellow receipt should be submitted to the Cosmetic, Device and Drug regulatory authority (CDDA) receiving station after the date has been imprinted on the receipt.

The application will then be entered into a register at the receiving station.

The sample license will be printed in three copies, each of which will be valid for one year from the date of issue, and the applicant will be able to pick it up at the reception point. (An additional copy will be included with the dossier.) [6]

➢ **Submission of application**

On submission, the application must meet the following requirements:

- the application must be in a box file;
- three different files must be prepared;
- the first page must include the following information: approved name, brand name, manufacturer's details, and importer's data.
- The application should be numbered from top to bottom and from bottom to top as well, with polio numbers inserted from top to bottom [7].

➢ . **Basic requirements**

- Index
- Acknowledgement
- Copy of sample import license
- 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 manufactured confirming that the device is in use there and for how long, and if not, reasons for not marketing it in the country of manufacture (Free sale certificate) - original or copy of a free sale certificate attested by an FDA/Medical Device Control Agency/ Sri Lankan embassy or foreign ministry is acceptable.
IV. Fully packaged examples of the devices List of nations with documentation to establish registration status in other countries, such as foreign country registration certificate
V. Label(s) sample with inner and outer boxes Catalogue of products to aid in product identification on the label, the lot number, production date, expiration date, manufacturer's name, address, and country of origin should all be listed [8].

2.6 Other Requirements

In addition to the basic documents/details listed above, the following documents should be submitted if necessary/if accessible.

1) For the products listed below, test results must be supplied.

- For products that come into direct contact with the bloodstream, such as disposable syringes, disposable needles, IV cannulas, IV catheters, and so on, independent analytical certificates from the Industrial Technology Institute (ITI) or a government-accredited laboratory in Sri Lanka (original report must be submitted) are required. Pharmacopeial standards must be followed while submitting test reports.
- - For specific items, such as plasters, gauze, feeding bottles, sanitary napkins, bandages, latex condoms, surgical gloves, etc., standardization reports from the Sri Lanka Standard Institution (SLSI) are required.
- - ISO accreditation is required to have access to the design, development, and production processes.

2) When submitting an application for absorbable sutures, the following parameters must be met.

All absorbable suture samples will be retained at the Cosmetic, Device and Drug regulatory authority (CDDA) for six (6) months before being sent to the appropriate specialist for review.

• Raw material suppliers and buying information should be disclosed.

• An independent laboratory as well as the producer shall offer an analytical certificate of the finished product according to relevant standards.

• Stability data for the finished items' whole shelf life should be provided.

3) If applicable, a certificate of permission from the appropriate authorities should be submitted.
4) For relevant products like as Glucometers, Hearing Aids, Ear and Forehead Thermometers, instructions for usage shall be supplied in three languages: English, Sinhala, and Tamil.
5) Relevant information should be supplied for high-cost cardiac devices in accordance with the "Guidelines for registration of Cardiac devices/stents" dated February 28, 2009, prepared by the committee formed to oversee the registration of High-Cost Cardiac Devices (HCCD). (A copy will be posted on the website.)
6) Relevant clinical trial data should be reported for borderline devices with therapeutic claims [7,8].

2.7 File Submission Procedure

- The application should be given to the pharmacist at the receiving point, who will provide a payment letter for the processing fees, which the applicant must pay at the ministry of health's Shroff counter. The shroff counter will give a yellow receipt, which should be attached to the dossier after being date stamped.
- The whole application should be delivered to the pharmacist at the receiving point with samples, where the pharmacist will review the dossier against a checklist and assess whether everything is in order.
- The dossier will be entered into a register with a serial number by the pharmacist (DVR no). & The acknowledgement, along with the DVR number, signature, and date stamp, will be returned to the local agent [9].

2.8 Applying for Import Licence

- After obtaining a registration, the applicant can apply for an import license by submitting a copy of the registration certificate and a request letter.
- Payment shall be paid at the MOH's shroff counter, and the yellow receipt should be delivered to the CDDA's receiving point after being date stamped with the aforesaid documents. Three copies of the import license will be issued. One copy will be given to the applicant, one will be attached to the application, and the other will be lodged with the Cosmetic, Device and Drug regulatory authority (CDDA).
- Every year, the import license should be renewed [10].

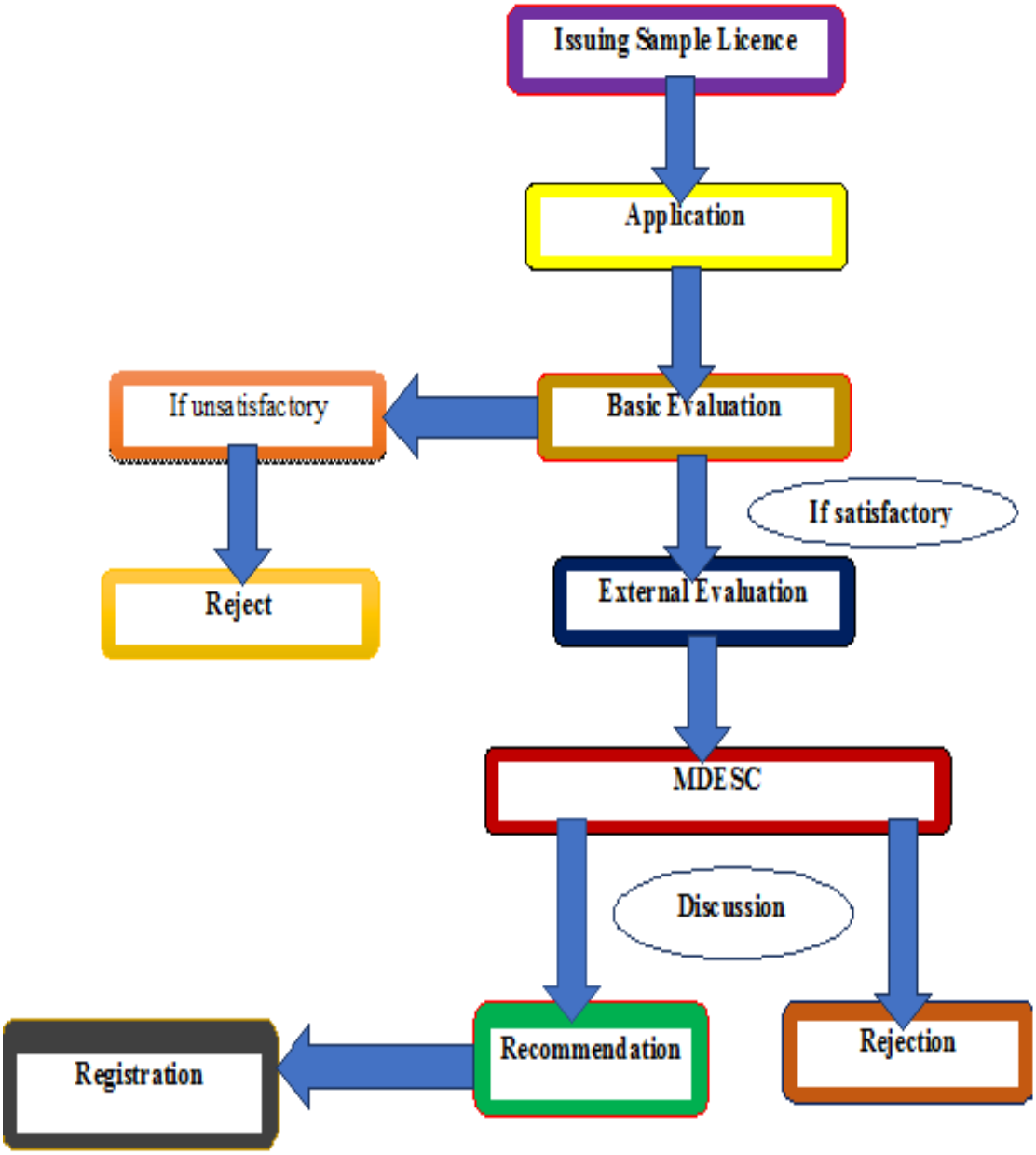

Fig. 1. Registration of medical devices

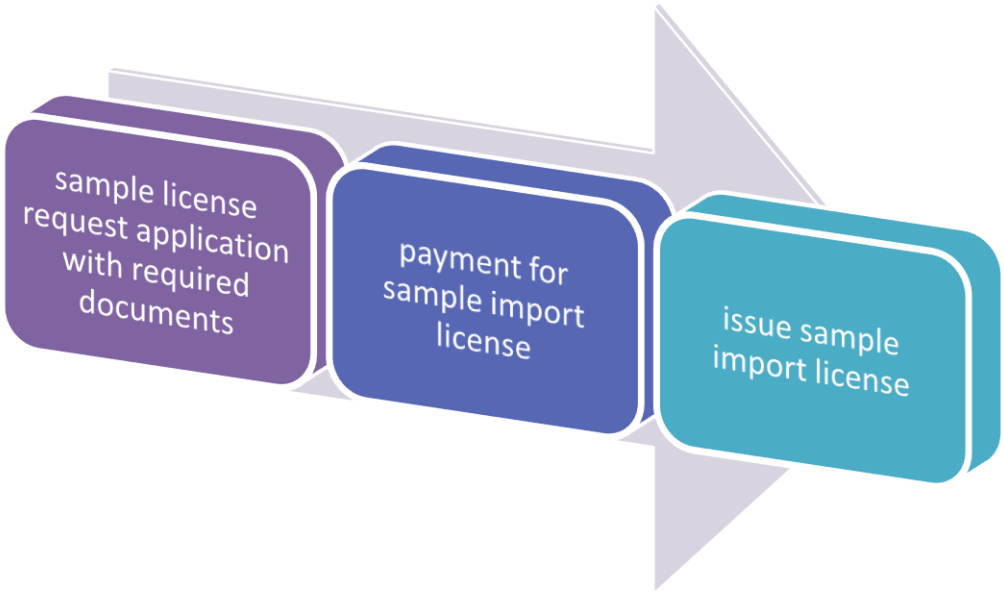

Fig. 2. Steps involved for registration of medical devices

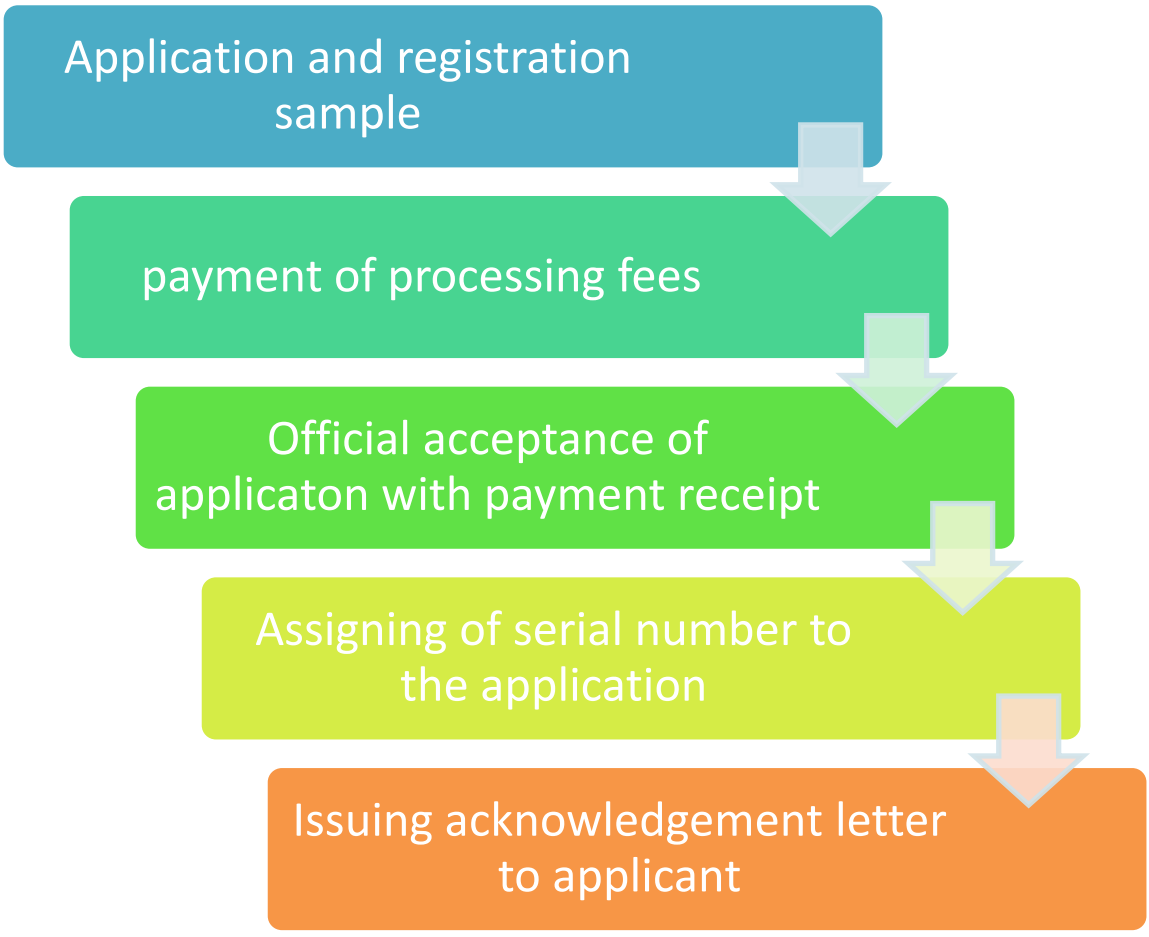

Fig. 3. Submission of registration application

2.9 Documents for Obtaining Sample Import License

- Form C of the Cosmetics, Devices, and Drugs Regulations has been completed (The Gazette of the Democratic Socialist Republic of Sri Lanka (Extraordinary) No. 378/3 of 1985)
- A copy of the applicant's business registration certificate [should include information about the board of directors and secretarial board (Form 48)]
- the manufacturer's letter of authorisation designating the Market Authorization Holder.
- Free Sale of Copies Certificate from the relevant health authority in the place of origin for a certain product
- Price comparison and CIF (cost-plus-in-freight) price (Separate applications should be submitted for different manufactures) [11].

2.10 Application for Medical Device Registration

- The application for registration must be made in Schedule I, Form A (link to forms) of the Cosmetics, Devices, and Drugs Regulations (The Gazette of the Democratic Socialist Republic of Sri Lanka (Extraordinary) No. 378/3 of 1985), together with the requisite documentation.
- All pages should be numbered from top to bottom and vice versa with an index, and documents should be written in English, in a legible font size, printed on one side A4 and presented in a hard file cover (Box file). If the original certifications or licences were granted in any other language by the competent authorities, certified English translations should be supplied.
- Registration applications are only processed if they are complete and meet the requirements.
- Separate applications should be made in respect of each device to be registered. [i.e., products containing different specifications, different brands]. Products of foreign manufacturers should be submitted through a Marketing authorization Holder [12].

3. APPLICATION FORMS

NATIONAL MEDICINES REGULATORY AUTHORITY

SRI LANKA.
120, Norris Canal Road, Colombo 10, Sri Lanka.

Application form for Waiver of Registration OF A MEDICAL DEVICE

For government institution ☐

For private institution ☐

1. Applicant Detail	
1.1 Name of the applicant	
1.2 Address of the applicant	
1.3 Telephone no.	
1.4 E – mail	

2. Details of the Product	
2.1 Official/Common name of the product	
2.2 Brand name (if applicable)	
2.3 Model (if applicable)	
2.4 Sizes (if applicable)	
2.5 Quantity	
2.6 Total cost	

3. Details of Manufacturer	
3.1 Name of the legal manufacturer & country	

3. 2 Name of physical manufacturer & country (If applicable)	

4. Details of the distributor (if applicable)	
4.1 Name of the Distributor	
4.2 Country	

5. Detail of local agent (If applicable)	
5.1 Name	
5.2 Address	
5.3 Contact detail	

6. Importer Detail (If applicable)	
6.1 Name	
6.2 Address	
6.3 Contact detail	

7. Past history of issued WOR of particular item (if applicable)	
7.1 WOR number (Letter No)	
7.2 Date of issue	

8. Reason for WOR (tick √)	
8.1 Delay NMRA Registration Short expiry of NMRA registration	☐
8.2 Registered sources not quoted	☐
8.3 Lowest price than registered item	☐
8.4 Registered product not complied with tender specification	☐
8.5 Manufacturer's name changed	☐
8.6 Government to Government agreement	☐
8.7 No registered sources	☐
8.8 Short shelf life of the product	☐
8.9 Research	☐
8.10Donation	
8.11 Other (If so reason should be mentioned)	☐

Remarks

9. Sample evaluation detail (if applicable)	
9.1Name of evaluator	
9.2 Designation	
9.3 Institution	

10. NMRA Registration Status (if applicable)	
10.1 Application No	
10.2 Date of submission	
10.3 Certificate of Registration No	
10.4 Validity period	

10.5 Any other NMRA documents/ reference No (if available)	

Declaration of the applicant	
I, ... the undersigned, hereby declare that all the information submitted with this application is true and correct and certify that all documents uploaded in support of this application are accurate and most recent as per to date. Signature : Date :	
Document required for Waiver of Registration (If available please tick "√") **Note : The NMRA may be required more data where necessary.**	
1. Letter of Authorization from the manufacturer	☐
2. Agency transfer letter issued by NMRA	☐
3. Sample import licence issued by NMRA	☐
4. Certificate of Registration issued by NMRA	☐
4. Free sale Certificate issued by Health Authority of Country of Origin of the Product	☐
5. ISO certificate for quality management system	☐
6. CE self declaration by manufacturer/ EC certificate for full Quality Assursnce system	☐
7. Labels of the product	☐
8. Product Information Leaflet / Catalogs	☐
9. Report of Technical Evaluation Committee (TEC)	☐
10. Approval of Procurement Committee	☐
11. Purchase order / Indent/Commercial invoice	☐
12. Registration of Medical Council – Sri Lanka	☐
13. Ethic review committee approval (Applicable for research items)	☐
14. Research proposal (Applicable for research items)	
15. No Objection Letter (NOL) from local agent	☐
16. Sri Lanka Custom Detained Document	☐
17. Recommendation of Professional bodies (Colleges/Institutions)	☐
18 Request of Professional bodies (Colleges/Institutions)	

4. CONCLUSION

According to the National Medicines Regulatory Authority Act No. 05 of 2015 the National Medicines Regulatory Authority shall be responsible for the regulation and control of registration, licensing, manufacture, importation and all other aspects pertaining to medical devices in a manner compatible with the National Medicines Policy; The National Medicines Regulatory Authority (NMRA) is responsible for ensuring that medical devices available in Sri Lanka are of acceptable quality, safety, and suitability for their intended use. The Medical Device Evaluation Committee (MDEC) formed under NMRA Act carries out technical evaluation of the medical devices forwarded for registration by considering the quality, safety, effectiveness,

need and cost of such devices. Persons who import or manufacture medical devices, or who have items imported or made on their behalf, must request for premarketing authorisation from the Cosmetics, Devices, and Drug Regulatory Authority (CDDA). The applicant is responsible for the product as well as the information provided in support of his product registration application. The National Medicines Regulatory Authority (NMRA) should be informed in a timely manner any change in product information during the course of evaluation, and after product registration, especially if the information pertaining to rejection/ withdrawal, additional data on product quality, effectiveness and safety or current Good Manufacturing Practice (cGMP) compliance of the manufacturers. The sample license will be printed in three copies, each of which will be valid for one year from the date of issue, and the applicant will be able to pick it up at the reception point. (An additional copy will be included with the dossier).

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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