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Review Article

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A Review on Approval and Registration Process of Medical Devices in Canada and India

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Abstract

A medical device is any device or material used to promote human health. Due to an increase in the prevalence of chronic diseases, irregular health examinations, and sedentary lifestyles, as well as an increase in cases of obesity, diabetes, neuro-based disorders, heart diseases, and chronic diseases linked to lifestyle disorders, the use of medical devices is increasing. There are many medical devices in use today, and different rules and regulations apply to their marketing in various nations. To be sold on the market, a medical device needs to have its marketing authorization granted by the appropriate country's regulatory organization. Medical device-based therapeutic therapy is offering technologically sophisticated alternatives for the management of a number of ailments. The ministry of health and family welfare as well as science and technology in India rely heavily on the CDSCO as their primary medical regulating body. This article has been produced to discuss how medical devices are approved and registered, as well as the recent market expansion. Medical equipment sales are strong but profitable in Canada. It has one-fifth the population of Brazil, yet spends nearly as much on healthcare every year. As a result, rules and regulations must be in place to oversee the sale of such products. standardized medical equipment in order to facilitate their swift approval as well as the registration of medical devices, registration across all markets is crucial.

Keywords: Medical devices, Health Canada, organization Structure of health Canada, CDSCO, Drugs and cosmetics act 1940 and its rule 1945, medical device lifecycle, approval process.

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1. Introduction

Medical Device in World Wide

A selection of harmonized definitions for medical devices have been proposed by the Global Harmonization Task Force (GHTF). The WHO states that medical devices can be used for one or more of the following particular purposes:

- Disease diagnosis, monitoring, therapy, and/or amelioration
- Identification, mitigation, monitoring, treatment, prevention, or payment for an injury
- study, replacement, or encouragement of any anatomical region or physiological process
- life's foundation and nourishment
- Controlling conception
- sanitizing medical devices (1)

Medical Devices are regarded as a critical component of Health Systems; the benefits they can provide continue to grow as they are required to prevent, diagnose, treat, and rehabilitate illnesses and diseases in a safe and effective manner. The steps involved in Medical Devices manufacturing, regulation, planning, assessment, acquisition, and management are complex but necessary to ensure their quality, safety, and compatibility with the settings in which they are used.(2)There are an estimated 2 million different types of medical devices on the global market today, divided into around 7000 generic device groupings.(3) The worldwide medical devices market was valued at roughly $488.98 billion in 2021 and is expected to reach an amazing US$718.92 billion by 2029. The rising prevalence of chronic diseases, combined with healthcare providers' increased emphasis on diagnosing and treating diseases earlier, is leading to an increase in the number of patients undergoing diagnostic and surgical procedures, which is encouraging companies to improve, develop, and create new innovative medical advancements. (4)

Table 1. Top 10 medical device companies in the world in 2022 based on revenue (5)

Rank	Medical Device Company	Revenue (Billions)
1	Medtronic	$30.12B
2	Johnson & Johnson	$22.95B
3	Abbott	$22.59B
4	Philips	$19.32B
5	GE Healthcare	$18.01B
6	BD	$17.11B
7	Siemens Healthiness	$16.93B
8	Cardinal Health	$15.44B
9	Stryker	$14.35B
10	Baxter	$11.67B

2. CANADA

A medical device is any instrument or component used to treat, diagnose or prevent a disease or abnormal physical condition. Veterinary or animal-related devices are not included under the category of medical devices. (6) The medical device market in Canada is well-established and highly diversified, with a preponderance of small and medium-sized businesses. The market is currently worth about USD$6.5 billion, and growth will continue through 2026 at a 2.1% annual rate. Less is known, though, about how Canada governs medical devices and its place in the world order. The contemporary Canadian regulatory system has a shorter history than the US medical device regulatory framework. While the origins of each country's food and drug regulation can be traced back to the early 20th century, Canada's present medical device regulatory paradigm is the result of a confluence of global factors and the quick advancement of technology. Its development has been fueled by a proactive regulatory strategy supported by an international consensus. This article chronicles the history of the Canadian regulatory system for medical devices to the present. The article's purpose is to provide information on the development of this framework, Canada's involvement in harmonization, the subtle regulatory distinctions within Canadian legislation, and Canada's present policy towards developing technologies. (7)

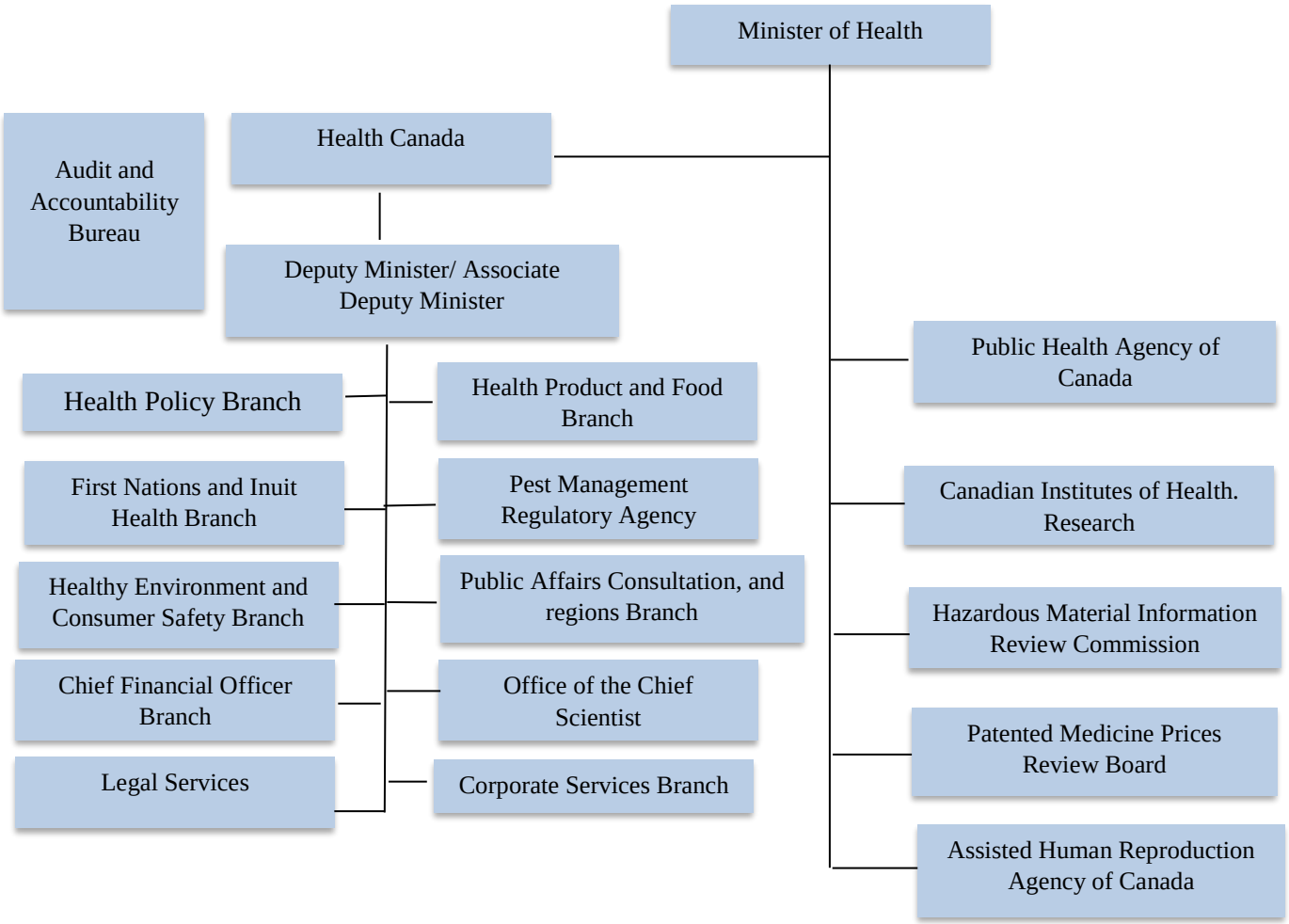

Figure 1. Organization structure of Health Canada (8)

2.1 Acts and Regulations

The Therapeutic Products Directorate (TPD) applies the Food and Drug Regulations and the Medical Devices Regulations under the authority of the Food and Drugs Act to ensure that the pharmaceutical drugs and medical devices offered for sale in Canada are safe, effective and of high quality. The TPD also administers fee regulations for drugs and medical devices under the authority of the Financial Administration Act. (9)

Canada's current regulatory framework has been in place since 1998. The foundation of the regulation's addresses:

- Classification for non-in vitro and in vitro medical devices
- Safety and effectiveness principles for all medical devices
- Requirements for manufacturer quality management systems

Some of the most significant differences between FDA and Health Canada requirements for medical device approval surround device classification, ISO, and reviewer discretion. You can begin to evaluate if obtaining Canadian approval is worth your effort by understanding how these differences are likely to impact your organization. (10)

2.2 Classification of medical Device

- Medical devices are classified according to Health Canada's risk-based system. There are four device classifications — Class I, II, III and IV — using a set of 16 rules found in Canadian Medical Devices Regulations. In vitro diagnostic (IVD) devices are also classified as Class I through IV using a set of nine rules. Device classification dictates both the type of license required for your product and quality management system (QMS) requirements. Class II, III and IV devices require a product-specific Canadian Medical Device License (MDL), and manufacturers must hold ISO 13485 certification under the Medical Device Single Audit Program (MDSAP). A Medical Device Establishment License (MDEL), held by the manufacturer or distributor, is required for Class I products. (11)
- Class I devices are approximately 40% of approved devices Every higher level of device class, like in the US, entails more regulatory scrutiny for your gadget. The criteria used to classify devices are a little varied, and they include things like potential contact with a patient's nervous or cardiovascular system, dependence on an energy source, and invasiveness. In Canada, class I devices can be sold without a license. Class II devices require a license application. To gain approval for a CLA class III device, organizations must submit a valid ISO 13485 certificate. Applicants for Class IV devices are required to apply, an ISO 13485 certificate, and other comprehensive safety data to Health Canada. Devices classified as Class IV are assessed in 75 days. (10)

Table 2. Classification of medical device (12)

Canadian Classification	Risk Level	Examples
Class I	Lowest	Reusable Surgical Scalpel, bandages, culture media
Class II	Low	Contact lenses, Epidural Catheters, Pregnancy Tests Kit, surgical Gloves
Class III	Moderate	Orthopedics implants, Glucose Monitors, Dental Implants, Hemodialysis Systems**,** Diagnostic Ultra sound Systems
Class IV	High	HIV Tests Kits, Pacemakers, Angioplasty Catheters

2.3 Application Fees

In Canada, Class I medical devices are exempt from device license applications and are not required to pay any fee. The fees for Class II, III, and IV devices could different significantly. According to Health Canada, the fees as of April 1, 2023, are as follows:

- Class II License Application $589 CAD
- Class III License Application $12,987 CAD
- Class IV License Application $28,165 CAD

These fees can vary slightly. For example, the application fee for a near-patient diagnostic in vitro Class III device is significantly higher at $27,666 CAD. (13)

2.4 Medical Device Registration in Canada

Firstly, the Manufacturers willing to sell their devices in Canada must obtain MDSAP certification. To market the devices in Canada, manufacturers must obtain a license. There are two types of licenses issued by Health Canada:

1. MDEL (Medical Device Establishment License) – Class I Medical Devices
2. MDL (Medical Device License) – Class II, Class III and Class IV Medical Device

2.5 Certification and Timeline

- The Medical Device Manufacturers willing to place their medical devices in the Canadian market must have MDL as well as ISO 13485: 2016.
- Time needed for MDEL – 120 Days
- Time needed for MDL – 15 Days (Class II Medical Device), Class III – 75 days; Class IV – 90 days.

The MDL license is intended for the device's approval. In contrast, the manufacturer, distributor, and importer company receive MDEL.

The medical device license is valid for one year.

2.6 Step by Step process to get registration of your medical device in Canada

If you are looking for a manufacturing partner who can help you enter the Canadian markets, then follow these steps:

- **Step 1**:

  Determine the class of your Medical Device. A device may fall into Class I, Class II, Class III, or Class IV

- **Step 2:**

  All the devices except Class I devices must comply with all guidelines of ISO:13485 certification

- **Step 3:**

  For all the devices under ISO: 13485 re-audits are done by an approved Auditing organization. New MDSAP will be issued on successful completion of the audit

- **Step 4:**

  Class I Medical Devices must acquire MDEL certification. Devices classified as Class II, III, and IV require MDL certification.

- **Step 5:**

  Submit the fees and documents as per your device requirement
  For Class I Medical Device you'll require to prepare mandatory procedures documents and pay the health Canada fees
  For Class II devices, submit an MDL application, Fees, labeling, Conformity declaration, and other major required documents

- **Step 6:**

  Health Canada reviews the application

- **Step 7:**

  Once the device is approved the information will be available on the health Canada website. You will also receive a letter from MDEL through mail.

2.7 Health Canada's Regulatory System

Health Canada's Regulatory System has crucial licensing requirements for medical devices. The regulatory process is divided into three phases including:

- Pre-Market Scrutiny
- Post-Market Surveillance
- In-process compliance & enforcement activities

- The Health Canada Regulatory system classifies Medical Devices based on risk they pose to the human life.
- For an instance Toungue depressors with minimal risk are kept under Class I Medical Device, Pacemakers that are meant for a more serious function and is supposed to be an equipment of high risk are kept under Class IV Medical Device.
- It would be mandatory for Class II, III and IV medical devices to have medical device license to be sold in Canada. Class Medical Device manufactured are required to exhibit Medical Device Establishment License. (14)

Once approved the manufacturer can sell medical device in Canada. The license is ongoing, but it will be cancelled if the yearly fee is not paid. (15)

2.8 Language of labeling and record:

Labeling for Medical Devices supplied to the general public must be provided in both English and French.

Labeling for Medical Devices for Professional Use must be supplied in English or French. (16)

2.9 License validity

The license for medical device is valid for one year. (17)

2.10 Opportunities in the Canadian market:

Since medical device imports make up 80% of the market, there are several opportunities for international producers in Canada. The most popular items are diagnostic equipment, patient monitoring equipment, supplies, patient assistance, orthopedic/prosthetic devices, and dentistry products. In Canada, the regulatory process is also well-established. If American producers are granted FDA approval, it might be easier for them to join the Canadian market. (18)

3. INDIA

The medical device market in India is small, heavily dependent on imports, and subject to complicated regulations. The market for medical technology and equipment is anticipated to increase from an estimated USD 3.7 billion in 2014 to USD 520 billion2 by 2020. India ranks fourth in Asia and among the top twenty markets worldwide in terms of market size, behind China, South Korea, and Japan. (19) Engineering and medicine come together in an unusual way in the medical device sector. It entails the construction of devices that sustain life inside the human body. Medical devices include surgical instruments, diagnostic tools like X-rays, CT scans, MRIs, and handheld ultrasound imaging devices; tools for life support like ventilators and other similar devices; and implants and disposables. Unlike pharmaceuticals, medical devices rely on a variety of technologies, including engineering, electronics, material sciences, and information technology. (20)

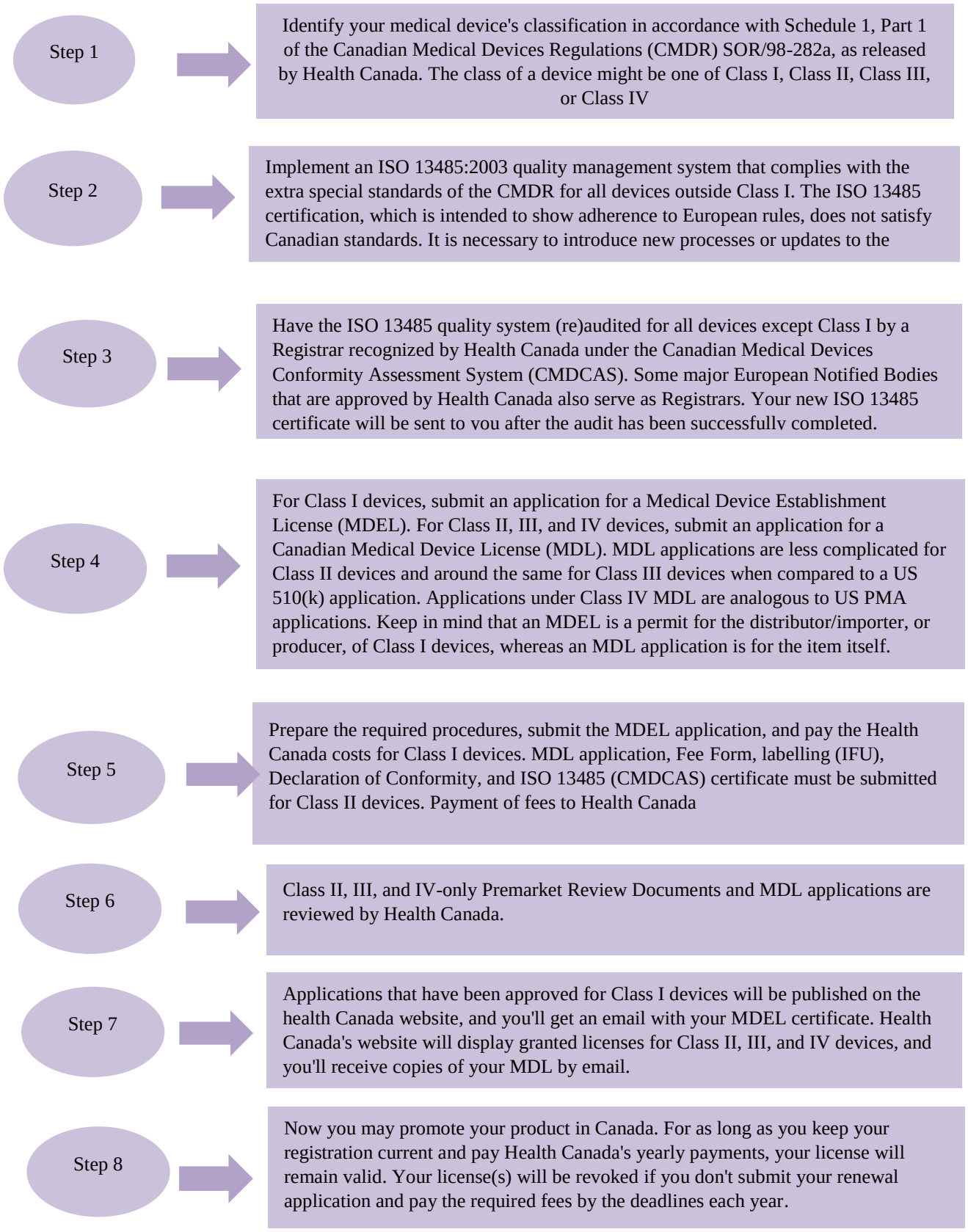

Figure 2. Medical Device Approval Process in Health Canada (18)

Note: Once the application is approved it will be posted on the Health Canada Website.

Medical devices that fall under the following definition will be governed by the "DCA and MDR" as of April 1, 2020. These include "all devices, including an instrument, apparatus, appliance, implant, material, or other article, whether used alone or in combination, including software or an accessory, intended by their manufacturer to be used especially for human beings or animals, which does not achieve the primary intended action in or on the patient."

I. Any disease or disorder diagnosis, prevention, monitoring, treatment, relief, or aid;

II. Any injury or disability diagnosis, monitoring, treatment, relief, or support;

III. Examining, substituting, altering, or supporting the anatomy or a physiological process;

IV. Providing for or maintaining life;

V. Sanitizing medical equipment; and

VI. Reproductive control (21)

3.1 Classification (22)

The new standards introduced a risk-based classification system in accordance with international regulations. These devices are categorized by the CDSCO, which periodically posts the list of categorized devices on its website. Manufacturers and importers must classify their products according to the categorization list. A higher grade of classification will be considered if the classification is higher in GHFT countries

Table 3. Classification of medical device

Type of device	Risk involved	Examples
Class A	Low-risk	Nasopharyngeal Catheter, Surgical Dressings
Class B	Low-moderate	Intravenous Catheter, Disinfectants
Class C	Moderate-high	Bone Cement, Bifurcation Stent
Class D	High	Copper T, Cardiac Patches

3.2 The Drugs and Cosmetic Act and Rules govern the following products as "Drugs" (Non-Notified Medical Devices) (23)

1. Blood Group Sera
2. Staplers, sutures, and ligatures
3. (CU-T) Intra Uterine Devices
4. Condoms
5. Tubular rings
6. Surgical Bandages
7. Umbilical cord tapes
8. Bags for blood and blood components

3.3 Need for CDSCO Registration

In addition to providing the company with legal support, CDSCO registration raises consumer confidence in a brand. The following are some essential justifications for why a company's medical device, IVD, or cosmetics industry needs CDSCO registration.

- To build a better brand image and attract a wider market of customers.
- To comply with regulatory norms of manufacturing, selling, distributing or importing these products.
- To guarantee the safety and quality of the products offered to customers.
- To minimize the legal and penal risks associated with post-licensing compliance and audit
- To tap into the innovations and quality products available overseas. (24)

3.4 Registration process of medical device in India

Step 1: Establish If Your Product Needs Registration.

In India, the Drugs and Cosmetics Act of 1940 and its Rules of 1945 govern the import, manufacturing, sale, and distribution of medical equipment. Currently, the aforementioned Act regulates 22 Notified Medical Devices. Spinal needles, cochlear implants, annuloplasty rings, tracheostomy tubes, syringes and needles, dental implants, surgical sealants, heart valves, cardiac stents, orthopedic implants, endotracheal tubes, and catheters are just a few examples of medical equipment that must be registered in India. These devices should go through the CDSCO (Documents required to register your medical device in India) registration process. These are not the only devices on the list. In some situations, the DCGI will analyze specific product information and issue a NOC to exclude a medical device from the registration process. This procedure might take anything from 4 to 12 weeks.

Step 2: Select a licensed Indian agent

According to Indian legislation, international producers must have a representative in India who will function as their point of contact with inspection authorities, help with the licensing and registration of devices, and aid with vigilance and the reporting of adverse events.

A manufacturer may designate an approved Indian agent to register on the manufacturer's behalf with the CDSCO. The Indian Agent will serve as a point of contact between you and the Medical Devices Division of the CDSCO. A wholesale drug license in categories 20B and 21B should be held by the designated Indian agent. The maker will hold the registration certificate and be able to choose numerous distributors throughout the nation.

Step 3: Fill up from 40 and submit the Regulatory Dossier.

To begin the registration process, a dossier with the requisite list of papers must be completed. The list of documents necessary is summarized below.

- form 40
- TR6 Challan
- Power of Attorney
- Schedule D
- ISO 13485 Certificate
- Full Quality Assurance Certificate
- CE Design Certificate
- Declaration of Conformity

- Free Sale Certificate
- Certificate of Marketability from GHTF countries
- Other Regulatory Approvals
- PMS report
- Plant Master File
- Device Master File

The CDSCO registration price for a single production site is US $1500, while the fee for a single device family is US $1000. The registration process can take anything from 6 to 9 months. If the product lacks a predicate in India, the processing time will be extended, and a special committee will be formed to examine the product's safety and efficacy for the Indian market.

Step 4 - Obtain a Form 41 Registration Certificate

After receiving the documents, the CDSCO will respond to the Indian Agent with the first enquiry letter in roughly three months.

Following receipt of the query replies, the CDSCO will either issue a following query letter or grant permission. The registration certificate is good for 3 years.

Step 5: Fill out Form 10 for an import license.

Distributor must submit the Form-10 directly to CDSCO. A Form 8 application must be submitted with a Form 9 that includes the registration certificate number. This procedure takes four to twelve weeks**.**

Step 6: Indian marketing

The product can enter the Indian market once the registration certificate and import license have been issued. The authorized Indian agent must notify the CDSCO of any changes, unfavorable occurrences, recalls in other nations, etc. as soon as they happen. (25)

3.5 Registration of new or innovative medical devices

Medical devices that are 'investigational devices' and subject to additional clinical investigation requirements and review, including establishing safety and effectiveness through clinical investigation in India, are novel to the Indian market in terms of materials, mode of action, or intended use. In a meeting with the CDSCO known as a Subject Expert Committee (SEC), they will ask additional questions and establish precise new standards that the manufacturer and license holder must fulfill in order to keep market access. (26)

3.6 Implementation of ISO-13485 in newly notified devices for registration requirement

Registration of a Newly Notified Medical Device requires a certificate of compliance with ISO-13485 (Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes). A registered manufacturer or importer of a medical device must always follow the requirements of ISO 13485. The established, documented, and implemented quality management system in compliance with ISO 13485 must be modified on a regular basis by an independent audit. (27)

3.7 List of requirements listed in:

CDSCO/MD/GD/CLAA/01/00 for the issuance of a Form-28 license for the manufacture of medical devices in India:

- Authorization Letter
- Requisite Fee (License fee Rs. 6000/- and Inspection fee Rs. 1500/-)
- Covering Letter
- Approved Manufacturing Premises Plan/Layout
- Site Master File (SMF)
- Device Master File
- Promotional literature, package insert, device label, etc
- A duly filled Form-27
- Constitution Details of form
- Full Details of competent and regular technical staff
- Specific Environmental Requirements
- Details of Standards
- ISO 13485:2003 Certificate (if any), CE mark (if any), any other approval (if any) (30)
- Requisite Fee (License fee Rs. 6000/- and Inspection)

- In India, applications for licenses to manufacture medical devices must be submitted is Form 27:
  - The responsible state drug licensing authority,
  - The CDSCO Zonal/Sub-Zonal office in question, as well as.
  - The CDSCO (HQ) of the Drug Controller General of India. (31)

3.8 Timeline

After submitting complete and proper data and fees to get the registration certificate, the registration of medical devices in India typically takes 6-9 months. Registration is valid for three years, and renewal applications must be submitted six months before the registration expires. (32) Validity of license in India for Notified Devices, three years after the date of approval.(33)

3.9 Labelling requirements

GSR703 complies with the 1940 Drugs and Cosmetics Act. (33)

A comprehensive set of the devices' labeling that complies with labeling regulations should normally be included in the dossier. Labeling information should include the following:

- The device's original box and labeling, including any accessory labels that may be present configuration;
- Usage instructions (prescriber's guide)

- Product shill; and
- Marketing materials.
- The label must adhere to the Drugs and Cosmetics Rules. (34)

3.10 Life cycle of medical devices:

The following steps are part of the medical device life cycle:

a) Determining the requirement for medical device development.
b) Create a plan for identifying the risk connected to the medical equipment.
c) Create a plan for risk minimization.
d) Offer Nomenclature
e) Evaluation of devices through clinical trials
f) Evaluate products against current medical device standards like ISO and IEC.
g) Evaluate for standards compliance.
h) Submit an application for authorization to the appropriate regulatory body.
i) After receiving approval, producers must train end users on how to operate the devices in accordance with the recommended procedures.
j) Perform out post-market surveillance and pinpoint the negative events linked to the devices.
k) Replacing equipment associated to the unfavorable incident. (35)

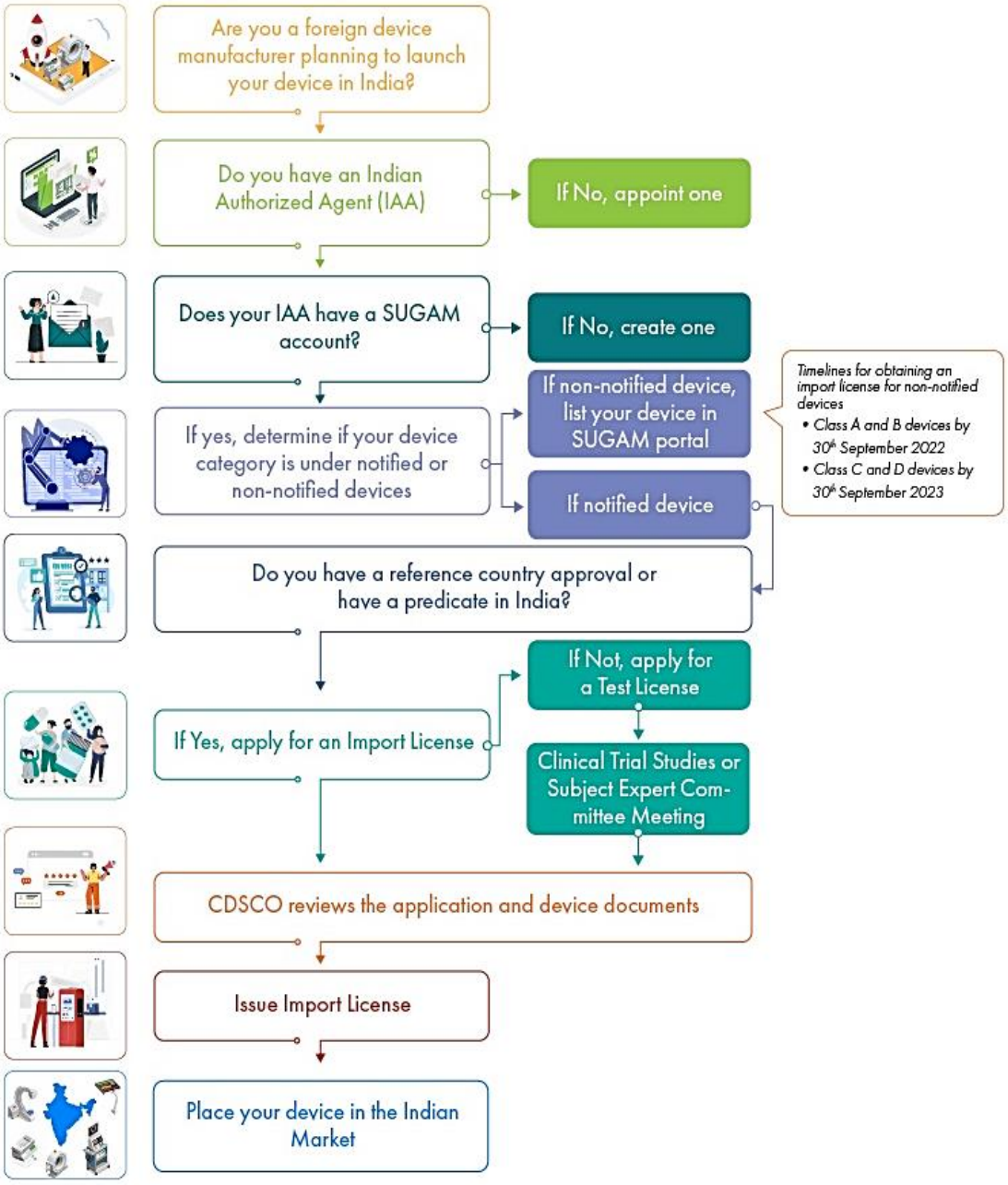

Figure 3. Device Registration process of foreign Manufacturing (28)

Medical device approval process in India (29)

Step 1

The Drug Controller General of India (DCGI) oversees the Central Drugs Standard Control Organization (CDSCO), which is a division of the Ministry of Health and Family Welfare. The Medical Device Rules from 2017 serve as the foundation for the regulatory framework for medical devices. In India, only a small number of IVDs and medical devices need to be registered. The CDSCO's List of Medical Devices and In Vitro Diagnostics Along with their Risk Class has a comprehensive list.

Step 2

Select a representative who is authorized to deal with the CDSCO on your behalf. To handle your registration and device importation in India, your Agent must be given Power of Attorney and possess a current wholesale license (Forms 20B and 21B/21C).

Step 3

The National Institute of Biological (NIB) requires in-country performance assessment for several IVDs.

Step 4

Prepare a device application (Form MD-15) that includes details about the manufacturing facility, the technical specifications of the device, the ISO 13485 certificate, the IFU, test results, clinical data, proof of approval in the US, EU, Australia, Canada, or Japan, and proof of approval in your home country (satisfied by CFS/CFG).

Step 5

Submit registration forms to the CDSCO and make payment. English must be used on all documents.

Step 6

A Technical Presentation might be required by the CDSCO while reviewing applications. Novel devices will also be reviewed by the SEC (Subject Expert Committee).

Step 7

A Registration Certificate will be issued by the CDSCO. Although the Certificate is perpetual, registration maintenance charges are needed every five years.

Step 8

Only your India Authorized Agent may import things when they have been approved. However, separate Authorized Agents can help you get several registrations for the same device

Figure 4. Medical device approval process in India

3.11 Opportunities in the medical devices in India

The Indian healthcare market is currently worth $65 billion and is expected to reach $100 billion by 2015. The need for complex medical diagnostics is expanding quickly as urban populations get older and larger. Two categories of high-end medical diagnostic equipment can be distinguished:

- MRI, PET, and CT scans used for in-vivo diagnosis
- Diagnostic equipment for IHC, FISH, PCR, q-PCR, MS, sequencing, and other tests is known as in vitro diagnostics (36)

India's medical supply market, which is Asia's fourth-largest at 3 billion USD, offers great commercial opportunities. for both international and international investors. In the early Domestic companies dominated this market in the 90s. players, however the situation has changed as a result of launch of the Indian market. Truth: 75% of the The sale of imported medical equipment or equipment that calls for imported materials the present-day Indian medical device industry MNCs predominate. manufacturers export more than 60% of their output. (37) The overall size of the Indian medical device market was estimated at INR 780 billion in 2020, and with a CAGR of 35.4%, it is predicted to grow to INR 3,550 billion by 2025. (38)

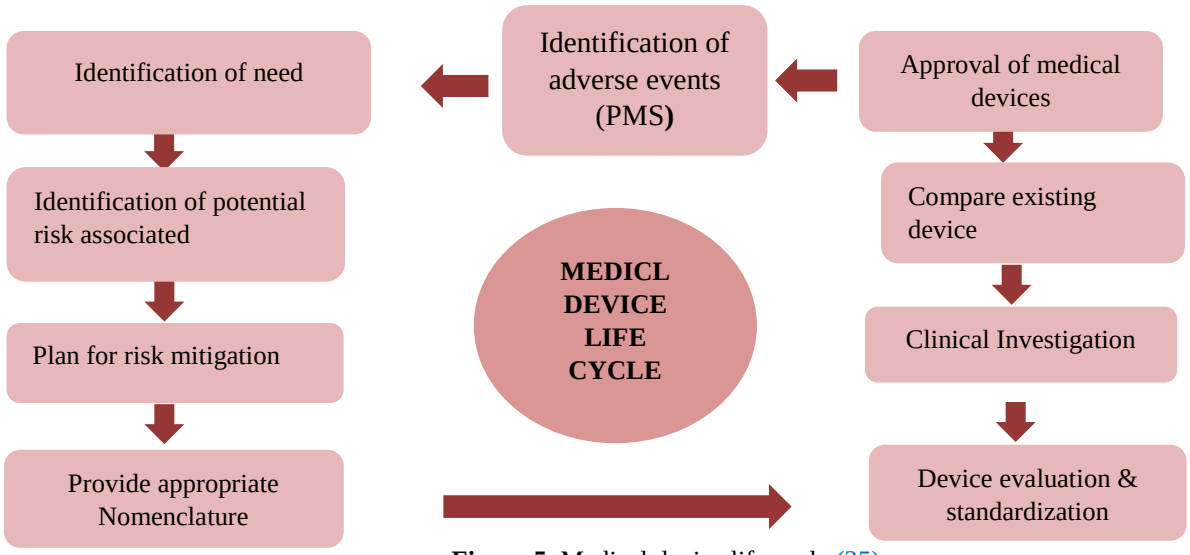

Figure 5. Medical device life cycle (35)

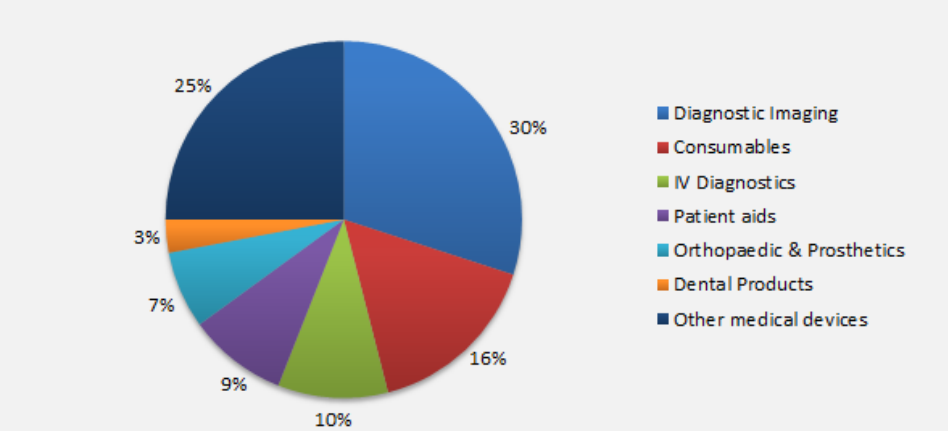

Figure 6. Medical device segment in India (38)

4. Comparison Chart of Medical Device in Canada and India

Table 4. Comparison Chart of medical device in Canada and India

Sr. No.	Contents of Comparison	India (39)	Canada
1	Regulatory authority	DCGI under CDSCO	Health Canada (40)
2	Regulation	Medical Device Rules, 2017	The regulation of medical devices in Canada is driven by The Food and Drugs Act (R.S.C., 1985, c. F-27) (41)

3	Class of medical Device	Four Class: Class A Class B Class C Class D	In Canada, medical devices are grouped into 4 classes based on the expected level of risk to a person's health and safety. Class I medical devices (e.g., a thermometer) pose the lowest risk to users. Class IV medical devices (e.g., a pacemaker) pose the highest risk. (42)
4	QMS Requirement	ISO13485:2016	CAN/CSA ISO 13485:2003(43)
5	Submission format	Paper / Electronic	Electronic Common Technical Document (eCTD) format or non-eCTD format. (44)
6	Language	English	English or French language (45)
7	Clinical evidence reports	Mandatory for class C and D devices	This document provides guidance to manufacturers of Class II, III and IV medical devices and regulatory representatives on the clinical evidence requirements for medical devices. (46)
8	In-country Clinical test	Not strictly required	Required (46)
9	Registration expiry	3 Years	1 year (14)
10	Time required for approval	6-12 months for the notified device	MDEL – 120 calendar days Class II – 2 months Class III & IV – 4-8 months (47)
11	On-site audits	Applicable (Notified Bodies)	Audits are carried out by auditing organizations of the Medical Device Single Audit Program (MDSAP) (48)

5. Conclusion

Understanding the Central Drug Standard Control Organization of India and Health Canada, the medical devices they use, their history, and the regulations is the major objective of this review. The Central Drug Control Organization (CDSCO) is responsible for carrying out the tasks imposed on the Central Government under the Drugs and Cosmetics Act. Health Canada carries out the medical device's regulations related to approval and registration in Canada. As a result, we think that there should be substantial support for all stakeholders in attempts to enhance the medical device regulation system in both academic and professional contexts.

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Conflicts of Interest

No conflicts of interest exist, according to the authors, with the publishing of this article.

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