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Comparative Study on Regulatory Requirements and Approval of Medical Devices in Australia & Canada

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Abstract

Medical device is evolving market so it is needed to be regulated to maintain its Quality, Safety and efficacy. Therapeutic goods administration (TGA) regulates medical devices in Australia whereas health Canada regulates medical devices in Canada. Registration of medical devices in Australia & Canada is also included along with its regulatory requirements. While manufacturing of medical devices clinical investigation and clinical evaluation are important to check safety and effectiveness of device and after release of device in market adverse event reporting is also important to determine cause of adverse event which has occurred and can cause serious health effects. Labels are necessary on medical devices as it provides information to the consumers about product. Instruction manuals and other things can also be given with medical device so that the device is handled properly. The barcodes can be placed on the labels so that the device can be tracked easily if any adverse event takes place.

Thus, as the title suggests it's a comparative study of medical device in Australia & Canada, we have differentiated points from guidelines which are slightly different in both countries. Case studies included also gives us idea about the adverse event which has occurred in recent years related to medical devices & also have added some recent updates related to medical devices in both countries.

Introduction

The phrase "medical device" refers to a broad spectrum of products, ranging from highly advanced computerised medical equipment and diagnostic medical devices to therapeutic medical devices with local applications, such as tissue cutting, wound wrapping, or propping open clogged arteries. These devices come in a broad variety of types and are crucial for patients' care, thus their production, distribution, and sale need to be controlled to guarantee their effectiveness, safety, and quality.

Australia is a significant and technologically advanced market for medical devices. Australia is one of the richest countries in the Asia-Pacific area and has the 11th-largest healthcare market in the world. The market value of the medical device business is approximately 4 billion Australian dollars, and it is growing at a 15% annual pace.

The Therapeutic Goods Regulations 2002, also known as the Regulations, went into effect on October 4th, 2002, and established a new GHTF harmonised regulatory structure. On October 4, 2002, the new system's transitional phase came to an end.

The Australian Government Department of Health and Ageing's Therapeutic Goods Administration (TGA) is in charge of carrying out the legislative requirements. The Australian public expects that the drugs and medical equipment available on the market will be secure, of the highest calibre, and at least on par with similar nations. The Therapeutic Goods Act 1989, which went into effect on 15 February 1991, has the purpose of creating a

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national framework for the regulation of therapeutic goods in Australia in order to guarantee the performance of medical devices and the quality, safety, and efficacy of medications.

The TGA defines a medical device as an instrument apparatus, appliance, material or other article intended to be used for human beings for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception
- In vitro examination of a human specimen for a medical purpose

The main repository for therapeutic products that can be lawfully imported into or exported from Australia is the Australian Register of Therapeutic Goods (ARTG). Sponsors for the medical devices listed in the ARTG assume responsibility for their legal supply to or from Australia.

Regulation of Therapeutic goods: Overall control of the supply of therapeutic goods is exercised through three major processes:

- **Pre market assessment:** Prescription drugs and medical equipment, which are considered to carry a higher level of risk, are tested for quality, safety, and efficacy. These items are included in the ARTG as "registered" products and are given an AUSTR number once they have been granted marketing authorization in Australia.
Many over-the-counter medications and low-risk medical equipment are examples of products that have their quality and safety evaluated. After receiving marketing authorization in Australia, these goods are "listed" in the ARTG and given an AUSTL number.

When determining the level of risk, various aspects are taken into consideration, including a product's potency, potential side effects for harm with continued use, toxicity, and the seriousness of the medical condition for which the product is intended to be used.

- **Licensing of manufacturers:** Australian manufacturers of medical products are required to have licences. Good manufacturing practises must be followed during the manufacturing operations. By guaranteeing that medications and medical devices are produced under clean, contaminant-free circumstances and that they adhere to defined standards of quality assurance, licencing and standards are intended to protect the public's health.

- **Post marketing vigilance:** Investigating complaints, testing items on the market in labs, and keeping an eye on compliance with the law are all post-marketing operations.

Medical devices in Canada

Canada is a highly developed technological country with a burgeoning medical device sector. The nation, which is situated close to the USA, the largest medical device market in the world, ranks first among the G7 countries as the most cost-competitive investment site in the medical devices sector. Nearly 500 companies in Canada produce medical devices, with the majority located in Ontario but also in Quebec and British Columbia.

In order to examine the conformity of regulated products, Canada has negotiated Mutual Recognition Agreements (MRAs) for medical devices with the European Union, Norway, Iceland, Switzerland, and Liechtenstein. Canada is a member of the North American Free Trade Agreement (NAFTA).

The sale of pharmaceuticals and medical equipment in Canada is governed by Health Canada, which is mandated by the Food and Drugs Act. The Therapeutic Products Directorate and the Health Products and Food Directorate are the two divisions of Health Canada. Therapeutic Products Directorate's Device Evaluation, Licensing Services, and Research and Surveillance departments make up the Medical Devices Bureau.

The Food and Drug Act's definition of the term "medical device" is "anything created, sold, or advertised for use in identifying, treating, preventing, mitigating, or reducing a disease, disorder, abnormal physical state, or its symptoms in a person; restoring, correcting, or changing a body function or body structure in a person; identifying pregnancy in a person; or caring for a person while pregnant It does not contain a

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medicine, but it does include a contraceptive method."
The phrase refers to a broad range of health or medical devices used for the prevention, treatment, control, or diagnosis of a disease or other abnormal physical state. Before approving their sale in Canada, Health Canada analyses medical devices to determine their quality, effectiveness, and safety. The Act states that any item made with animal use in mind is not considered a medical device.

According to the risk of injury from abuse, the complexity of the design, and the characteristics of use, the regulatory authorities classify medical devices into various categories. These categories are defined differently depending on the nation or location. Authorities are aware that some gadgets are sold alongside medications, and they take this into account when regulating these combination items. Medical product marketing is made easier and patient and staff safety is maintained by categorising medical equipment according to their risk.

The MDEL

- helps identify companies that are selling medical devices in Canada
- ensures standards and procedures are in place to mitigate health and safety risks
- helps identify who manufactured the devices being sold by the MDEL holder

Companies must have created written policies proving they can respond to complaints and carry out recall, when necessary, in order to acquire an MDEL. Procedures must be in place for manufacturers and importers to notify Health Canada of recalls and major medical device issues.

Without a current medical device licence, Class II, III, or IV medical devices cannot be sold or imported into Canada (MDL). Devices that are not regulated and have not been examined for their safety, effectiveness, or quality could be harmful to Canadians' health.

Registration of medical devices in Australia

➢ The main repository for therapeutic products that can be lawfully imported into or exported from Australia is the Australian Register of Therapeutic Goods (ARTG). Sponsors for the medical devices listed in the ARTG assume responsibility for their legal supply to or from Australia.

➢ Unless they are exempt or excluded, sponsors of medical devices must make sure they are covered by the ARTG before giving them.

➢ You must build a relationship with the maker of the medical device before you submit an application to include it in the ARTG in order to:

○ Assemble the documents or information necessary to prove that the type of medical equipment conforms with Australian regulatory criteria.

○ As long as you are supplying the device in Australia, you must give any documentation or information regarding the regulatory, technical, clinical, and safety elements of the device that we may need at any time.

○ Inform you of any issues, safety warnings, or recalls that might occur while using the equipment.

Regulatory requirement to apply for new medical device

➢ The sponsor is in charge of submitting the medical device for ARTG registration. To comply with the essential principles outlined in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002, the medical device must first be categorised in accordance with the Australian system, and appropriate quality control systems must be implemented.

➢ The manufacturer is required to participate in a post-marketing surveillance system, but the sponsor is the accountable legal entity and must do so as well.

➢ Class IIa, IIb, III, and AIMD medical devices must have a quality management system in place before a conformity assessment certificate may be obtained. Use of standards is advised but not required.

➢ Australian standard orders can be utilised however, the global ISO standards are also acceptable. Depending on the kind of medical equipment, standards for quality management systems (ISO 13485), risk management (ISO 14971), clinical trials (ISO 14155), and biocompatibility (ISO 10993) are advised.

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➢ The product's manufacturer must have conducted a formal risk study. This complies with Australian Essential Principles 1 and 2, which guarantee the security of medical devices.

➢ A conformity assessment certificate from the TGA or another notified body outside of Australia, a Declaration of Conformity, and an application to add the medical device to the ARTG are required in order to register a medical device there.

➢ Medical equipment class I that do not have a measuring function or are meant to be given in a sterile state are exempt from needing the conformity assessment certificate.

➢ Manufacturers with a CE certificate must give TGA following information:

○ Copies of the current CE certificates hold by the manufacturer

○ Copies of the Initial Certification audit report

○ Copies of the current CE design Examination or Type Examination Certificate, if applicable

○ Copies of the Design Examination or Type Examination reports issued by the Notified Body in support of the certificate, if applicable

○ Evidence of close out of non-conformities

➢ In addition, the manufacturer must deliver the data specified under Section 5.0 of the attached form's requirements for quality system documentation, an essential principles checklist that has been completed, a risk management report, clinical evidence, labelling, usage instructions, and promotional materials.

➢ The manufacturer must additionally submit a Design Dossier, which is a collection of quality management system design and development records demonstrating conformance to fundamental principles, for class III devices and AIMDs.

➢ Upon reviewing this data, TGA might undertake a condensed assessment of the quality system or, in rare instances, an on-site audit.

➢ At the very least, the information that comes with the medical gadget must be in English. A paper containing usage instructions is not required if a device is class I or class II and may be used safely for its intended purpose without them.

➢ The registration is valid for five years.

Clinical investigation of medical devices in Australia:

Definition: Systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device is known as clinical investigation.

Particularly in relation to the Essential Principles (EPs) and the need for clinical data to show conformity with the EPs, Australian law regulates medical devices. Clinical investigative studies, literature reviews, and data from clinical experience are all examples of sources of clinical evidence (including post-market data). The TGA is aware of the hierarchy of clinical evidence and will take into account whether the degree of the clinical evidence is appropriate for the risks and benefits that the device poses.

Medical device regulations: The Medical Device (MD) Regulations describe the EPs (and the conformity assessment methods) and call for the use of clinical evaluation procedures as well as clinical evidence:

- The EPs are listed in Schedule 1. According to EP 14, every medical equipment must possess clinical proof proving that it conforms with the relevant EP rules.
- The conformance assessment techniques are outlined in Schedule 3. Part 8 of the Schedule, in particular, details clinical evaluation processes for manufacturers to gather and assess clinical data.
- Regulation 3.11 stipulates that the clinical assessment processes, i.e., those described in Part 8 of Schedule 3, must also be applied to a device in order to show that the device conforms with the applicable EPs, and in particular, EPs 1, 3, and 6, subject to certain restrictions.

A medical device must be created and developed in a way that doesn't jeopardise the health and safety of users, other people, or patients' clinical conditions. When compared to the intended benefit

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to the patient, the risks associated with using the device must be reasonable and compatible with a high degree of protection for their health and safety.

A medical device's design and construction must adhere to safety criteria while taking into account the generally accepted state of the art. This necessitates the identification and mitigation of any dangers related to the use of the equipment.

Risk must be reduced by manufacturers to the barest minimum. To guarantee the continuous safety of a medical device, manufacturers must establish, implement, document, and maintain a quality management system (QMS). Throughout the lifecycle of a medical device, risk management is an ongoing process that necessitates constant update.

Clinical Evidence Requirements

Clinical data and their interpretation in relation to a medical device make up clinical evidence. It ought to give the TGA a precise and up-to-date picture of the level of scientific understanding regarding the particular device under consideration as well as the therapeutic modality to which it relates. By demonstrating that a medical device works as intended and that all identified undesired effects and hazards were mitigated during the design and development process, an acceptable benefit-risk profile for the device may be proven.

This section describes the importance of clinical evidence in determining the performance and safety of a medical device, the procedures for providing clinical data, and the expectations for the level of specificity and breadth of evidence needed for various medical devices.

When to submit clinical evidence

Although it is usually given to the TGA when requesting a conformity assessment certificate or applying to be included in the ARTG, as well as during post-market surveillance or reviews, clinical evidence must be accessible throughout the lifecycle of a device. It should be periodically reviewed and updated if new data on performance and safety is discovered through research, literature, or clinical experience in relation to the targeted device or similar devices. The TGA may request and review this clinical evidence at any time.

Higher classified devices will be examined more closely by the TGA to ensure their performance and safety. The categorization, design, and usage of the device are all important considerations when determining the nature, kind, and scope of the evidence necessary to show compliance with the applicable EPs. Every medical device must be supported by clinical data that is relevant for the device's use and classification and that demonstrates compliance with the applicable EP regulations, according to EP 14.

Clinical Evaluation

Clinical evaluation is a series of continuing procedures for assessing and analysing clinical data to confirm the safety and clinical efficacy of the device when used in accordance with the manufacturer's instructions. The clinical assessment should make it possible to draw conclusions about how well the device balances risks and benefits.

Clinical evaluation is a continuous process carried out over the course of a medical device's lifecycle. The performance, safety, and benefit-risk profile of the device must be reviewed by the manufacturer on a regular basis, and the clinical data must be updated as necessary.

Studies produced by manufacturers, sponsors, or individuals who have benefited financially or otherwise from manufacturers, sponsors, shall be given due consideration. The study report and the critical evaluation found in the CER should both include a discussion of the degree of manufacturer or sponsor involvement.

Analysis of the Clinical data

The goal of analysis is to determine whether the evaluated data sets for a medical device collectively show the device's safety, clinical performance, and/or effectiveness in connection to its intended use.

The clinical expert should provide feedback on the manufacturer's risk analysis and risk management strategy and determine the benefit-risk profile of

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using the device in the intended target populations for the desired purposes.

The Clinical Evaluation Report (CER), taking into account all of the clinical data on the device, should unmistakably show a favourable profile based on current knowledge and the state of the art in the pertinent medical domains.

The Clinical Evaluation Report (CER)

A CER that contains the following information should be created following the clinical evaluation process:

- scope and context of the evaluation
- clinical data
- data appraisal and analysis
- Judgements made on the medical device's functionality, safety, and presentation (including labelling, patient information, and IFU) when used for its intended purpose.
- a benefit-risk determination.

An impartial entity, such as a regulatory authority, should be able to view the clinical evaluation report as a stand-alone document and determine whether or not it complies with legal standards for clinical evidence.

Throughout the device's existence, the CER should be updated periodically to include new information, such as clinical experience data and revised benefit-risk evaluations. Keep track of any revisions and adjustments

Common errors in Clinical evaluation report

There are several typical mistakes or shortcomings in CER submissions that can be prevented, including:

1. Absence of the CER's essential elements and/or absence of referenced attachments and appendices.
2. Between documents, there are discrepancies in intended purpose, indication, and claims; for instance, the application, IFU, and CER list distinct intended purposes.
3. Intended purpose, indication and claims not supported by clinical data.
4. Lack of knowledge regarding the device's regulatory history in other nations, including any recalls, withdrawals, removals from the market, suspensions, or cancellations, and the reasons behind them in any jurisdiction.
5. Information on similar devices is absent, and/or substantial equivalency is not shown (if relevant)
6. Literature, post-market data, and clinical investigation data using the device or a related device that are insufficient or incomplete (if relevant)
7. Inadequate critique and summary of the totality of evidence provided for the device
8. No post-market information, such as failures, complaints, vigilance reports, negative events, or adverse events in circumstances where this information is accessible.
9. CER not signed by clinical expert and CER not dated or out-dated
10. Inappropriate selection of clinical expert
11. CV of clinical expert not provided

Supporting Documents

The following supplementary records (which may be supplied separately or as part of the CER) supplement the proof offered in the CER:

1. Risk assessment and risk management documents
2. The device's labelling, instructions for use (IFU), product handbook, and all other accompanying materials
3. Additional information on the device
4. Pre-clinical data (if relevant)
5. Clinical investigation reports (full study reports or peer reviewed journal articles)
6. Literature search and selection strategy
7. Pivotal articles from the literature review
8. Post-market surveillance reports.

With special focus on the indications for use, target population, contraindications, and adverse events, the clinical evaluation should analyse the supporting documents and whether they are consistent with the clinical evidence.

Clinical investigation reports should contain the following information: the design, subject selection and inclusion/exclusion criteria, population

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demographics, duration, safety and performance data, adverse events and complications, patient discontinuation, device failures and replacements, tabulations of data from all individual subject reporting forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analysis.

Adverse event Reporting of Medical devices in Australia

Adverse event: An incident involving a medical equipment that fits the following description is referred to as an adverse event:

- Death of a patient, health care provider, user or other person
- A patient, healthcare professional, user, or other individual suffering from a serious injury or degeneration, such as:

  - A life-threatening illness or injury
  - Permanent impairment of a body function
  - Permanent damage to a body structure
  - A condition that requires medical or surgical intervention to stop permanent body structure damage or permanent impairment of a body function.

Reportable adverse event

The sponsors of a medical device must automatically report adverse events or near-adverse events to the TGA Incident Reporting and Investigation Scheme in order for that medical device to be included under section 5.7 of the Therapeutic Goods (Medical Devices) Regulations 2002

It is significant to remember that reporting an issue does not release a manufacturer, sponsor, user, or patient from responsibility for the incident or its effects.

Only unfavourable incidents that take place in Australia must be reported to the TGA. The TGA is not required to receive reports of adverse events that happen abroad for Australian-made devices, although records of these events should be made available upon request.

Near Adverse event:

A "near adverse event" is a situation involving a medical device that might have resulted in a death or serious injury but did not because, for instance, of the prompt intervention of a healthcare professional. When defining an event as a near unfavourable event, the following criteria must be met:

- An event associated with the device occurred
- If the event occurred again, it might lead to death or serious injury as outlined above.

- **Post market data:**
- For pre-market and post-market TGA evaluations and reviews, post-market data should be given. Manufacturers, sponsors, regulatory authorities, and others may gather post-market data. The sponsor must report all post-market information available to them.

- The quantity of units sold (or unit demand) globally since introduction, stratified by country (especially if numbers are low) or geographic area, and by year. Note that this might not always be suitable for high usage gadgets, those with multiple components, or those that have been on the market for a long time.

- The number and types of complaints made to the manufacturer about the product, as reported, as determined by analysis, and, in the case of new products, stratified by the year the complaint first occurred.
- The overall number of adverse events (including serious adverse events) and vigilance data reported to regulatory agencies, both as reported and as confirmed on analysis, and classified by type (for example, device malfunction, use error, inadequate design or manufacture) and clinical outcome (for example, death, amputation, surgical procedure required, no harm to patient).

- Any regulatory actions, such as voluntary or required recalls, recalls for product correction, removals, suspensions, withdrawals, or other corrective actions taking place in the market for IFU changes or other reasons, cancellations of the

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device anywhere in the world, or any other corrective and preventive actions

Adverse event reports: Anyone can report an adverse event

- Reports by consumers and health professionals are voluntary
- Sponsors are required to disclose any negative events connected to a medical device that they are aware of.

The TGA evaluates the risk of each adverse event report involving a medical device. TGA professionals in science, engineering, and medicine analyse the reports that were chosen for inquiry. The TGA uses reports from those regulatory authorities in its investigation of safety signals related with medical devices supplied in Australia, and communicates medical device adverse event reports with them as necessary.

Sponsors of medical devices listed in the ARTG are urged to electronically submit reportable adverse events through the TGA TBS portal's Medical Device Incident Reporting MDIR application.

Post-Market Clinical Follow-up (PMCF) studies

In order to address particular questions (uncertainties) about the safety, clinical performance, and/or effectiveness of a device when used in accordance with its labelling, a PMCF study is one that is conducted after marketing authorization. A portion of post-market data comes from PMCF research. Additional clinical data can be gathered through PMCF trials to answer the remaining questions regarding the device's potential advantages and lingering concerns.

A Clinical Investigation Plan should be presented when PMCF investigations are planned as part of a risk management strategy, including as part of premarket applications. Clinical research studies for pre-market applications in Australia may also be based on PMCF studies completed after clearance in other jurisdictions.

post-market regulatory actions

Information about marketing approval suspension or cancellation (in any country) and recall actions is also useful. Recall procedures are typically used to address concerns with devices that have flaws or other problems that are related to their performance, quality, or safety.

The two main categories of recall actions are (a) correction, which may require temporary removal from use, such as for revisions to the IFU, and (b) permanent removal of subpar, substandard, or dangerous medical devices from use. Hazard notifications may be necessary for implanted devices.

The TGA's Uniform recall procedure for therapeutic goods describes the full range of recall actions (URPTG). On the System for Australian Recall Actions (SARA) page of the TGA website, you can find more details on recall actions.

Labelling of medical devices in Australia

For the purpose of assisting manufacturers and sponsors in fulfilling their commitments, the material clarifies the labelling requirements for medical equipment. Labelling is the term used to describe the labels and other details that must be included with a medical device.

Manufacturers Obligations

The person in charge of the design, production, packaging, and labelling of a medical equipment is known as the manufacturer. Manufacturers are required to have proof that their medical equipment complies with all applicable Essential Principles, including those pertaining to labelling and usage instructions.

The label, usage instructions, and other information that come with the medical device must include the name and address of the manufacturer.

An Australian Declaration of Conformity is a document that manufacturers must sign in order to market a medical device in Australia. The manufacturer's choice of conformity assessment techniques to prove that their medical device

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complies with the Essential Principles is specified in the Australian Declaration of Conformity. Depending on which conformity assessment processes a manufacturer has employed, different ongoing requirements apply.

Sponsor's Obligations

According to the law, a "Sponsor" is the entity legally in charge of listing a medical device on the Australian Register of Therapeutic Goods (ARTG). Sponsors must comply with Regulation 10.2 and make sure their name and address are printed on every gadget they ship into Australia.

The sponsor's name and address must be mentioned in a brochure that is delivered with the device if it is not practical to publish these details on the device itself or the packaging used for the device. In order to comply with Regulation 10.2's regulatory requirements, sponsors may decide to attach a label to the device's package that includes their name and address.

The inclusion of a label on the device's packaging to satisfy Regulation 10.2 does not imply that the sponsor satisfies the criteria for manufacturer status. If you are a sponsor and you attach a label to the device to comply with Regulation 10.2, the label may not in any way tamper with the device or hide the manufacturer's instructions.

Information which is necessary to be added on label

1. The manufacturer's name, or trading name, and address.
2. The gadget's intended usage, who the device is meant for, and what types of patients are intended to utilise it (if this information is not obvious).
3. Sufficient information to let a user to recognise the device, or, if applicable, the packaging's contents.
4. Any particular handling or storage requirements applying to the device.
5. Any warnings, restrictions, or precautions that should be taken, in relation to use of the device.
6. Any special operating instructions for the use of the device.
7. If applicable, an indication that the device is intended for a single use only.
8. An indication, if relevant, that the item has been created specifically for a certain person or health professional and is only meant to be used by that person or health professional.
9. When describing a sterile gadget, include the word "STERILE" and details on the sterilisation process.
10. The batch code, lot number or serial number of the device.
11. A declaration of the date, if relevant, up to which the device may be used safely, with a clear indication of the month and year.
12. If the information contained with the device is missing the details listed in item 12-a, a declaration of the device's date of manufacture should be included (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable).
13. If applicable, the words 'for export only'

Unique device identification system

The use of a Unique Device Identification (UDI) system for medical devices will increase patient safety. The system is a first for Australia. If deployed throughout the healthcare and supply chains, the UDI system will enable tracking and tracing of medical devices, even those that have been implanted in patients. If there is a problem with the safety of a medical equipment, clinicians will be able to alert patients right away.

A key method for enhancing the identification and traceability of medical devices is the Unique Device Identification (UDI) system. Other improvements intended to enhance the efficiency of pre-market evaluations of medical devices and management of post-market safety-related operations will be made possible in large part by the UDI.

An internationally recognised device identification and coding standard is used to establish the unique device identifier (UDI), which is a string of numeric or alphabetic characters assigned to a particular model of a medical device.

Registration of Medical Devices in Canada

- The national agency responsible for keeping an eye on and assessing the efficacy, reliability, and calibre of diagnostic and therapeutic medical devices in Canada is the Medical Devices Directorate (MDD).

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➢ MDD guarantees the quality, safety, and efficacy of medical devices sold in Canada. This is accomplished by a combination of pre-market evaluation, post-approval surveillance, and manufacturing process quality systems.
➢ Before being sold in Canada, some devices require a medical device licence. All sorts of medical devices have been divided into groups depending on the risk involved in using them in order to identify which gadgets require a licence. With this method, all medical devices are divided into one of four kinds. The least risky devices are those in class I, like wheelchairs. The largest possible risk comes from Class IV devices, such pacemakers.
➢ Manufacturers of Class II, III, and IV devices must get a medical device licence before they can market a device in Canada. Despite the fact that Class I devices are exempt from licencing, they are still overseen as part of the establishment licencing procedure.

- **Review Process**

➢ When a business decides they want to commercialise a medical device in Canada, there are a few steps to take:

1) Manufacturer submits an application for a medical device licence
2) the amount of information needed depends on the class of the device
3) MDD reviews the application
4) MDD issues a licence if the information provided meets the requirements of the Medical Devices Regulations.

➢ The manufacturer has two options if MDD decides not to grant a licence: they can submit a revised application again with the updated facts, or they can file an appeal.

➢ The time it takes to review an application depends on the class of the device:

1) Class II licence applications: 15 calendar days
2) Class III licence applications: 75 calendar days
3) Class IV licence applications: 90 calendar days

Regulatory requirements to apply for new medical device

As a Canadian National Standard, Canada has designated ISO 13485:2003 as CAN/CSA-ISO 13485:2003. For class II devices, the quality system must meet CAN/CSA-ISO 13485:2003 specifications, with the exception of design. Class III and Class IV devices require a quality system that complies with all CAN/CSA-ISO 13485:2003 criteria, including design.

➢ Information required in the Application for a New Medical Device License is:

○ Device classification
○ Device name
○ Application history
○ Name and Address of Manufacturer as it appears on the device label
○ Mailing address for Regulatory Correspondence
○ License Application Type
○ Device Preferred Name Code (Optional)
○ Device Usage Category
○ If the device contains a drug
○ Purpose of the device
○ Device detail
○ List of Standards Complied with in the Manufacture of the Device (Only class II)
○ Attestation of Safety and Effectiveness (Only class II)
○ Attestation of labelling (Only class II)
○ Evidence of safety and effectiveness (Class III and IV)
○ Attestation of drug safety, efficacy and quality
○ Signature

Clinical investigation of medical devices in Canada

Clinical evaluation is a series of ongoing activities that employ scientifically reliable techniques for the evaluation and analysis of clinical data in order to confirm the safety, clinical performance, and/or effectiveness of the medical device when used in accordance with the manufacturer's instructions.

When is clinical evaluation undertaken

Clinical evaluation is a continuous process carried out over the course of a medical device's life cycle. It is first carried out during the development of a

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medical device to determine the data that must be created for regulatory purposes and will determine whether a new device clinical trial is required, along with the outcomes that must be investigated. The process is then repeated on a regular basis as new data on the medical device's safety, clinical performance, and/or effectiveness are discovered through use.

According to ISO 14971:2007, this information is included into the continuing risk management process and may lead to modifications to the manufacturer's risk assessment, clinical investigation documentation, Instructions for Use, and post-marketing activities.

Why is clinical evaluation important

In general, it is anticipated that the manufacturer will have shown that the medical device performs as intended when used in accordance with its labelling (i.e., information provided by the manufacturer) and that the known and foreseeable risks are minimised and acceptable when weighed against the benefits. Any claims made on the medical device's efficacy, clinical performance, or safety should be adequately substantiated by data.

Manufacturers are required to create and maintain surveillance programmes as part of their quality management system that regularly monitor the safety, clinical performance, and/or efficacy of the medical device with reference to post-market activities.

This ongoing clinical evaluation process should enable manufacturers to share any information that is significant to the benefit-risk analysis of the medical device or that would necessitate the need for labelling changes regarding contraindications, warnings, precautions, or instructions for use, etc. with conformity assessment bodies and regulatory authorities in accordance with local reporting requirements.

What is the scope of a clinical evaluation

The clinical review is founded on a thorough examination of all pre- and post-market clinical data pertinent to the planned use of the questioned device, including safety, clinical performance, and/or effectiveness data. This includes information relevant to the device in question as well as any information pertaining to devices the maker claims are comparable.
The evaluation must also take into account any clinical claims made regarding the device, the acceptability of the usage instructions, and the appropriateness of product labelling and information (especially contraindications, precautions, and warnings).

The clinical evaluation should cover any design elements that raise unique performance or safety issues (such as the presence of therapeutic, human, or animal components), the intended use and application of the medical device (such as the target treatment group and disease, proposed warnings, contraindications, and method of application), as well as any specific claims made by the manufacturer regarding the safety, clinical performance, and/or effectiveness of the product.

It is expected that the risk management documentation will describe the hazards connected to the medical device and how those risks have been handled. The significance of any hazards that remain after the manufacturer has used design risk reduction measures is anticipated to be addressed during the clinical evaluation.

Who should perform the clinical evaluation?

An individual or individuals who are appropriately qualified should conduct the clinical evaluation. A manufacturer must be able to defend the selection of the assessor by citing credentials and proven experience.

As a general rule, evaluators ought to be familiar with the following:

- The device technology and its application
- Research methodology (clinical investigation design and biostatistics)

Diagnosis and treatment of the illnesses that the medical gadget is meant to diagnose or treat.

The Clinical Evaluation Report

After the clinical assessment process is complete, a report that describes the evaluation's scope and

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context, its inputs (clinical data), the appraisal and analysis stages, and its conclusions regarding the device's safety, clinical performance, and effectiveness should be produced.

The clinical evaluation report needs to have enough details enable a third party to read it independently (e.g., regulatory authority or notified body). The report's outline must be clear:

- The medical device's intended application, the technology it is based on, and any guarantees made about its effectiveness, clinical performance, or safety.
- The nature and extent of the clinical data that has been evaluated
- What the cited data (recognised standards and clinical data) show about the device's safety, clinical performance, and/or effectiveness.

Adverse event reporting of medical devices in Canada

The incident reporting requirements in the Regulations are designed to enhance monitoring, decrease the frequency of occurrences involving medical devices in Canada, and guarantee that the risk that problematic devices pose to Canadians is managed effectively. The Regulations permit Health Canada to participate in international alert systems since both Health Canada and its regulatory partners have similar reporting obligations.

Manufacturers, importers (as defined in Section 61.1 of the Regulations), and authorization holders (as defined in Section 61.2) are regarded as Health Canada's reporters of incidents. The patient, user, or other individual who first brought the incident to the reporter's attention is the complainant.

How do I decide if the incident is reportable to health Canada

It's likely that the reporter won't have access to sufficient details to assess if an incident merits reporting. The reporter in this situation ought to use reasonable attempts to find more data to support the choice. Where appropriate, the reporter should speak with the treating physician or other relevant health care provider and use all reasonable steps to locate the device for inspection.

It is not necessary to report to Health Canada foreign incidents involving Class I devices that occurred before the specific incident that led to the decision to report a corrective action to a foreign regulatory authority (or to the foreign regulatory authority's request that a corrective action be undertaken). But the case for taking any further corrective action should take into account these instances.

Health Canada should be informed of the specific foreign occurrence that led to the decision to take corrective action. Foreign occurrences that happen after a corrective action has been decided upon and that share the same underlying cause as the incident that prompted that decision do not need to be reported to Health Canada unless they lead to the implementation of a second, distinct corrective action.

What are criteria to determine reportability

The reporter learns of information about a device-related incident that has taken place. Information from device testing conducted by the manufacturer, user, or another party may be included in this.

The reporter should consider the following factors when determining if the device and the occurrence are related:

- The opinion, based on available information, from a health professional
- Information concerning previous, similar incidents
- Complaint trends
- Any other information held by the reporter

It could be challenging to make this decision when there are several gadgets and medications involved. If there is doubt about whether an incident is reportable after becoming aware of it, the reporter should nonetheless submit a report within the timeframe necessary for that kind of incident.

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Multiple incidents with the same device:

The use of a medical device that results in reportable incidents that affect one or more patients, users, or other people on the same or different dates must be reported to Health Canada as distinct incidents because each occurrence involved a unique event. To the contrary, a reportable incident involving a specific run or rack of analyses (containing samples from one or more patients) should be reported to Health Canada as a single incident because the entire rack of analyses represents a single event in the case of a medical device, such as an automated chemistry analyser.

Use error: All potential usage error instances must be assessed by the reporter, as is the case with all reported device complaints. Risk management, usability engineering, design validation, and corrective and preventative action procedures should all be considered in the review. To make sure that these factors are taken into account, importers may need to coordinate their review with the manufacturer. Results ought to be made available to Health Canada upon request.

Reporting of use error: Errors in the usage of medical devices are receiving more attention internationally. The reporter must assess incidents involving use mistake and record the findings. The manufacturer's quality systems corrective and preventive action requirements, design validation, usability engineering, and risk management methods can be used to limit these kinds of occurrences. By their very nature, occurrences involving usage error frequently entail some degree of uncertainty regarding the underlying cause, but the manufacturer can limit the risks by working with Health Canada.

- **What information must be submitted in the preliminary report:**

The reporting must provide information required by Section 60(2)(a) so that the device involved in the incident can be quickly identified. The name of the device (for instance, the trade name), the medical device identification, the device catalogue number, the device licence number, the model number, the serial number, the lot number, etc. must all be included.

The reporter must identify the device's manufacturer and importer (where applicable) in accordance with Sections 60(2)(b)(i) and (ii). Name and address of the device's importer and maker are among the details needed (as appropriate). In order to ease contact for any further information regarding the occurrence that may be required by Health Canada, extra information also includes the reporter's name, title, phone number, and facsimile number.

According to Section 60(2)(f), the reporter must disclose, if known, the names of any further medical devices or accessories connected to the occurrence. Any additional gear that was utilised alongside the gadget or close by it is referred to here. Information on medications taken concurrently with the device is also helpful. The reporter must submit their initial comments regarding the incident in accordance with Section 60(2)(g). The comments should address the investigation's preliminary results and evaluate the danger to patients and users.

What information must be submitted in the final report

According to Section 61(2)(a), the reporter must provide a description of the incident, as well as the number of people who have died or seen a substantial decline in their health. In order for the description of the incident in the final report to be clear and comprehensive, all new information acquired since the submission of the preliminary report must be included. This would also cover a discussion of whether the device was fixed or replaced after the preliminary report was submitted, as well as the specifics of the fix or replacement.

According to Section 61(2)(b), the reporter must provide a thorough justification for the actions taken in response to the incident as well as an explanation of the incident's primary cause. The explanation must be precise, supported by solid science, and compatible with the presented facts and any pertinent information. The reason must provide proof that the suggested course of action will both address the issue and reduce the likelihood that it will arise again.

The final report must provide specifics of the risk communication plan if users of the device need to be informed. This can be achieved by making reference to the recall notification that was already sent to Health Canada in the final report.

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Inadequacies in reporting

It should be noted that Health Canada may need to ask more questions, seek more information, or conduct compliance checks if any of the aspects listed in this guideline document are missing from an incident report. The Health Products and Food Branch Inspectorate will receive incomplete incident reports from reporters, for which Canada Vigilance - Medical Device Problem Reporting Program is regularly obligated to request more information, in order to assess regulatory compliance.

Summary reports

A summary report of the data related to the topics mentioned in paragraph that the licensee learned about or received during the past 24 months, in the case of a Class II medical device, on a biennial basis.

A brief report of the information regarding the matters mentioned in paragraph that the licensee received or learned of during the previous 12 months, in the case of a Class III or IV medical device, on an annual basis.

If, when compiling the summary report, the licensee comes to the judgement that new information regarding the advantages and hazards of the medical device has emerged, they must notify the Minister in writing within 72 hours of reaching that conclusion, unless it has already been done.

Labelling of medical devices in Canada

To help non-in vitro diagnostic device makers adhere to the labelling requirements set out in Sections 21 through 23 of the Medical Devices Regulations (Regulations). The labelling criteria mentioned in sections 21 through 23 of the Regulations must be met by medical devices that are sold or imported for sale or use in Canada. When creating labelling material for non-in vitro diagnostic equipment, it must be used.

11.1 Section 21 of the Medical Devices Regulations - General Labelling Requirements:

1. Section 21(1)(a) - The name of the device

Each type of device, such as a system, medical device family, medical device group, or medical device family, needs to be given a name. The device licence is given for the device name that appears on the label and may refer to more than one device. a collection of administratively related devices offered for sale under a single name. a collection of gadgets with the same generic name that also specifies their intended applications. With the help of this name, the user can recognise it and set it apart from other gadgets of the same kind.

2. Section 21(1)(b) - The name and address of the manufacturer

The licence is issued to the manufacturer named on the label. The label may also include the importer's or distributor's name and address. If more than one name is listed on the label, it must be made clear how each name relates to the product, as is the case with private labelling contracts between a manufacturer and a distributor or importer. The manufacturer listed on the label receives the device licence. The name and address should be in sufficient detail to serve as a postal address.

3. Section 21(1)(c) - The identifier of the device, including the identifier of any medical device that is part of a system, medical device group, medical device family or medical device group family

The identifier, which works in conjunction with the device's name to differentiate one from all others, is a special number that the manufacturer assigns to each product. It could be a barcode, model number, or catalogue number, and in conjunction with the name, it will provide for a certain amount of control and traceability in the marketplace.

4. Section 21(1)(d) - Control number in the case of a Class III or Class IV device

The word "control number" refers to a special set of letters, numbers, or symbols, or any combination of these, that the manufacturer assigns to a medical device that can be used to trace the production, packing, labelling, or distribution of a unit, lot, or batch of finished devices.

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The control number enables the device to be tracked from the point of manufacture through the final user, including a potential implant recipient. It offers the maximum level of traceability together with the device's name and identity. For only Class III and Class IV devices does this apply. Although Class I and Class II devices are exempt from this requirement, the control number improves post market traceability.

5. **Section 21(1)(e) - If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units**

The purpose of this requirement is to give the user detailed information about the contents of the package so they may compare similar items and make an educated decision. The user will be able to choose a size that suits his or her needs thanks to the information. Metric or SI (International System of Units) units should be used to express units.

6. **Section 21(1)(f) - The word “Sterile” if the manufacturer intends the device to be sold in a sterile condition**

The word "Sterile" must be printed on the label if the producer sterilises the equipment and intends for it to be sold in a sterile state.

7. **Section 21(1)(g) - The expiry date of the device, where applicable, to be determined by the manufacturer based on the component of the device that has the shortest projected useful life**

The expiration date is based on the lifespan of the least stable component. The conclusion of studies showing that the device will function as intended and meet its specifications up until that time must serve as the basis for the expiration date. The year, month, and day should all be expressed using the standard international format (ISO 8601 Data Elements and Interchange Formats Information Exchange-Representation of Dates and Times) (in two digits). A hyphen should be used as a separator between the three parts of the date (-)

8. **Section 21(1)(h) - Unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use**

This part requires the manufacturer to briefly describe the function of the item as well as the population subgroups for which it is meant to be used, for instance, "For use in adults over the age of 18." The device's function and the manufacturer's intended goal are both referenced in the purposes and uses. The maker or representatives may convey this objective through the labelling claims, advertising, or written or oral statements.

There are some gadgets whose usage instructions are well known; hence such labelling may not be required. The device, as labelled, must produce results that are clinically significant in order for the purposes and uses to be supported by reliable scientific evidence. The manufacturer may choose to give a summary of pre-clinical or investigational testing results for Class III and Class IV devices along with the required citations.

9. **Section 21(1)(i) - The directions for use, unless directions for use are not required, (i) in the case of decorative contact lenses, for the device to be used safely, and (ii) in the case of any other medical device to be used safely and effectively**

This is the information given to the layperson and/or the health care professional so they can use the gadget to obtain the intended result without unnecessarily harming themselves or another person. The Instructions for Use should be written at a level appropriate for the intended users' training.

10. **Section 21(1)(j) - Describe any special storage conditions applicable to the device**

Depending on the temperature, humidity, or light levels in the environment, some devices may deteriorate quickly and may need to be stored in a specific way to avoid this. This information must be made available to the user so they may assess whether such storage conditions are reachable or within their budget. Provide storage temperatures in degrees Celsius.

11. **Section 21(2) - The information required pursuant to section 21(1) of the Regulations shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user**

All of the labelling components outlined in the aforementioned sections must be presented on the

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label in a prominent and understandable way. Under the usual circumstances of purchase and usage, the label information should be worded in clear language and presented in a way that the purchaser or expected user is most likely to understand.

11.2 Section 22 of the Medical Devices Regulations - Outer Package Labelling for Sale to the General Public:

1. Section 22(1)(a), (b) - Labelling for devices intended to be sold to the general public

The label's information must be shown on the package's exterior. For the intended user to choose the device wisely and to identify a device post-market in the event of a product recall, the information must be readily available.

2. Section 22(2) - Labelling for devices too small to display all the required information

This section takes into account the possibility that the device's packaging could occasionally be too small to display the usage instructions. The usage instructions may then be included as a package insert with the item. In these cases, the user should be directed to this additional labelling by information on the package's exterior.

11.3 Section 23 of the Medical Devices Regulations - Language Labelling Requirements

• Section 23(1), (2), (3) - Official Language Requirements Devices sold to the general public

Information required under clauses 21(1)(a) and (e) to (j) for medical devices sold to the general public must at the very least be written in both English and French. In these circumstances, the usage instructions must be provided at the time of purchase in both of the official languages

Comparative study of differences between regulatory requirements of medical devices in Australia & Canada

Table 1. Classification of medical devices in Australia & Canada [18]

AUSTRALIA	CANADA
Not Mentioned	• **Lowest risk devices: -** Class I medical devices e.g., Bandages, culture media
• **Low risk devices: -** Class I medical devices e.g., Tongue depressors.	• **Low risk devices: -** Class II medical devices e.g., Contact lenses, Catheters
• **Low to Medium risk devices: -** ❖ Class I devices supplied sterile e.g., Sterile surgical gloves ❖ Class I devices with a measuring function. e.g., Medicine cup with specific units of measurements. ❖ Class IIa medical devices e.g., Dental drills.	Not Mentioned
• **Medium to high-risk devices: -** Class IIb medical devices e.g., Surgical lasers.	• **Moderate risk devices: -** Class III medical devices e.g., Orthopaedic implants, Dental implants.
• **High risk devices: -** Class III medical devices e.g., Prosthetic heart valves	• **High risk devices: -** Class IV medical devices e.g., HIV test kits, Pacemakers.
• **Very high-risk devices: -** Active Implantable medical devices e.g., Pacemakers, Artificial Heart.	Not Mentioned

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Table 2. Differences between regulatory requirements for clinical investigation of medical device in Australia & Canada

AUSTRALIA	CANADA
1. TGA has drafted its own clinical investigation guidelines for medical devices.	1. Canada follows IMDRF guidelines for clinical investigation of medical devices.
2. Clinical investigation of medical device in Australia is included under schedule 1 & 3 of "Therapeutic Goods (Medical devices) regulations 2002"	2. Clinical investigation guidelines in Canada are included in Part 1 (General requirements) of "Medical device regulations" (SOR/98-282)
3. In Australia medical device must comply with essential principles in medical device regulations which set out requirements relating to device safety and performance.	3. In Canada, there are no such essential principles there are different rules for clinical investigation and to check safety and performance of devices.
4. All medical device supplied in Australia must have clinical evidence sufficient to demonstrate the level of safety and performance when used for intended purpose.	4. In Canada, only class II, III and IV medical devices must have clinical evidence to demonstrate level of safety and performance when used for intended purpose.
5. In case of Australia there are two types of clinical evidence i.e Direct clinical evidence and indirect clinical evidence in compliance with essential principles.	5. In case of Canada there are no such types of clinical evidence.
6. In Australia clinical experts are needed for the formation of clinical evaluation report and the expert must be highly qualified.	6. In Canada, there is no need of clinical experts for formation of clinical evaluation reports. Reviewers are appointed to prepare the reports.
7. When clinical investigation is done in Australia it must comply with guidelines of "National Statement of Ethical Conduct in Human Research"	7. When clinical investigation is done in Canada it must comply with "Medical devices Directorate" (MDD) which is Canada's regulator of medical devices for human use.
8. In Australia clinical investigation studies and approval nearly takes about 140 working days after application is received.	8. In Canada, clinical investigation studies and approval nearly takes about 120 working days after application is received.
9. In Australia substantial equivalent devices are also required with comparable devices for clinical investigation studies.	9. In Canada, only comparable devices are required to carry out clinical investigation studies.
10. In Australia, firstly device registry should be done with ARTG and then clinical investigation studies should be done.	10. In Canada, clinical investigation study should be done first and then device should be registered.

Table 3. Differences between regulatory requirements for adverse event reporting in Australia & Canada

AUSTRALIA	CANADA
1. TGA follows its own document to report the adverse event of medical devices.	1. Health Canada follows guidance document of adverse event reporting which is prepared by GHTF committee.
2. The guidelines for adverse event reporting are included under section 5.7 of "Therapeutic Goods (Medical devices) regulations" 2002	2. The guidelines for adverse event reporting are included under section 59 & 61 of "Medical device regulations" (SOR/98-282).
3. Only adverse events that occur in Australia should be reported to TGA. Overseas adverse event need not to be reported.	3. If adverse event occurs for particular devices in foreign it needs to be reported based on its seriousness and records should be maintained.
4. Annual reports in Australia are submitted for class IIb, implantable class III and active implantable medical devices (AIMD)	4. Annual reports in Canada are not required for any class of medical device. Final report which is submitted is sufficient.

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5. There is another department under TGA which looks after the safety of medical devices i.e "Advisory Committee on safety of medical devices" (ACSMD)	5. The health Canada is the sole authority which looks after the adverse event and the safety of medical devices throughout Canada.
6. There are eight exemption rules that apply to the requirements to report the adverse events in Australia.	6. There are no such rules that apply to requirements to report the adverse events in Canada.
7. If there is serious threat to the public health it should be reported in 48 hours after you become aware of event.	7. There are no such provisions in case of Canada if the incident is occurred then only it can be reported.
8. Final report in Australia should be submitted within 120 calendar days after submission of initial reports.	8. In Canada there is no such deadline to submit the final report but should be submitted as soon as the study is done.
9. The follow up report of adverse event of medical device in Australia should be reported within 30 calendar days.	9. If there is death or serious health condition due to medical device in Canada it must be reported in 30 calendar days.
10. Sponsors of medical devices included in Australian Registry for Therapeutic Goods (ARTG) are strongly encouraged to submit reportable adverse events through "Medical Device Incident Reporting" (MDIR) application contained with TBS portal.	10. Sponsors of medical devices included in health Canada are encouraged to submit reportable adverse event through the portal of "Medeffect Canada" which comes under health Canada.

Table 4. Differences between regulatory requirements for labelling in Australia & Canada

AUSTRALIA	CANADA
1) Essential principle 13 of Schedule 1 of the "Therapeutic Goods (Medical devices) Regulations 2002" outlines requirements for label which must be provided with medical devices	1. The labelling requirements for medical devices is listed under section 21-23 of "Medical devices regulations" (SOR/98-282)
2) Catalogue number and Control number are must for all class of medical device in Australia for traceability purpose.	2. Catalogue number and Control number must be included for class III and class IV devices only. It's not mandatory for class I and class II devices.
3) Any type of letter, number, symbol or number in symbol used in information must be legible and at least 1mm high.	3. There is no size or height limit on label in Canada. Although the label must be clearly visible to purchaser.
4) In Australia in case of class III and class IV devices there is no need to include pre-clinical or investigational testing results.	4. In class III and class IV devices manufacturer may wish to include a summary of pre-clinical or investigational testing results with appropriate results
5) If the device is small then the direction for use should be added with the help of implant card and patient information leaflets.	5. The package that contains the device may be too small to allow the directions for use to be displayed. The directions for use may then accompany that product package insert.
6) Australia uses "Unique device Identification system" which allows tracking and tracing of medical devices including those that have	6. Canada is still not using "Unique device identification system" but has started to study the possibility of implementing a UDI system in Canada.

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been implanted in patients.	
7) There is no need to provide instructions for use for class I and class IIa medical devices.	7. There are some medical devices for which indications for use are commonly understood and such labelling may not be necessary.
8) The label should be in English and should be precise and easily understandable.	8. The label should be either in English or French if it's sold in Canada and level of language should be appropriate to educational level or expertise of intended user.

Current update on medical device in Australia (News)

1. New compliance dashboard for post market medical device reviews: (19 October 2020)

The method through which the Therapeutic Good Administration (TGA) interacts with sponsors will change as of October 19, 2020. To replace the current procedure of responding to a post-market review and emailing the TGA with the relevant documentation, a new Post Market Review Compliance Dashboard has been created.

Summary of changes:

- In the new dashboard, which can be accessed through TBS, sponsors will be able to directly reply to post-market reviews.
- The new dashboard offers a quick and safe way to respond to post-market reviews while also centrally preserving the data. Additionally, since the TGA teams will have access to this information in the dashboard, it will be simpler to access reviews—both active and closed—and there will be no need to provide information to them again.
- The dashboard eliminates the need to distribute files via the Cloud, email, or shipping USBs by allowing users to upload pertinent files up to 15GB (per file) in size.

2. Regulation impact statement: Unique device identification system for medical devices (27 October 2020)

The Australian Government announced on October 6 that it will create a Unique Device Identification (UDI) database for medical devices as part of the 2020–2021 Budget. The Therapeutic Goods Administration (TGA) will be in charge of maintaining the UDI database, and the data can be used to facilitate tracking and tracing of medical devices in order to enable prompt clinical and regulatory steps in the event that medical device safety issues are discovered.

The Department of Health has confirmed that the Review of Medicines and Medical Devices Regulations (MMDR) undertook a procedure and analysis akin to a RIS in accordance with the Government's Regulation Impact Statement (RIS) criteria. The OBPR determined that the independent review's analysis is adequately related to the UDI proposal. The Department has predicted that the implementation of this measure won't result in an increase in the regulatory burden.

The certification letter is now available on the central RIS register run by the Office of Best Practice Regulation (OBPR) at Unique device identification system for medical devices.

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Current updates on medical devices in Canada (News)

1. Medical device no longer considered to have urgent public health need status: Notice for industry (July 2021)

Health Canada is determining whether specific kinds of medical devices are urgently needed for public health as the pandemic develops. As the pandemic develops and if the availability and demand for particular device types alter, we will periodically re-evaluate the condition of these gadgets. This strategy enables us to concentrate resources more effectively on evaluating COVID-19 medical devices that are urgently required so that Canadians can get them as soon as possible.

A UPHN evaluation is performed on each IO application for a device. A screening deficiency letter will be sent to the applicant in the event that there is insufficient proof of a UPHN for their medical device. Such proof includes, for instance, a certification from a Canadian health authority confirming the existence of a UPHN for that medical equipment. Applications that lack sufficient proof of a UPHN will be rejected by Health Canada.

2. Clinical trials for medical devices and drugs relating to Covid- 19 regulations (March 2022)

The Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations (Regulations) were published on March 2, 2022. They came into effect on February 27, 2022, following the repeal of Interim Order No. 2 respecting clinical trials for medical devices and drugs relating to COVID-19 (IO No. 2). IO No. 2 was made on May 3, 2021.

On May 3, 2022, the terms of IO No. 2 are scheduled to expire. The Regulations, which went into effect on February 27, 2022, will take their place. The Regulations will continue to simplify the licencing and execution of COVID-19-related clinical trials by keeping the pathway outlined by the IO. They will continue to enforce the requirements for trial participants' health and safety and ensure the validity of trial data in addition to lowering the administrative load. All clinical trials applications (and changes) for COVID-19-related medicines and medical devices must be examined by the FDA within 14 days, according to the Regulations. Additionally, reviews and clearances for COVID-19 clinical trials are given first priority by research ethics committees

Discussion

A medical device is an object which can be used for treatment, cure and diagnosis of disease. There is vast development in the medical devices in recent years and technical innovations also took place. Medical device classification may be different in different countries according to there risk class. To determine the safety and efficacy of medical devices the device must undergo clinical investigation and detailed study should be carried. TGA looks after clinical investigation of medical devices in Australia whereas health Canada regulates medical devices in Canada. There is strict procedure for clinical investigation in Australia as compared to Canada.

When the device enters the market, the companies should have a watch on there product and determine the adverse event shouldn't occur. The adverse event reporting guidelines are developed by the respective countries where the devices are studied about the adverse event which has occurred according to that actions such as recalls can be taken. Labelling is also important for medical devices as it provides information about the device to consumers. Labelling guidelines are implemented which tells us about what information is important on the label. Specially Australia uses UDI system to keep watch on the devices by applying barcode on the labels for the purpose of traceability.

The security of medical devices is also very important as it can have negative potential hazards to the consumers and can lead to serious consequences. Before approving a medical device, the regulatory agencies should thoroughly examine all the documents and should not compromise with human health. Thus, when we compare both countries to study various guidelines, we understand that Australian guidelines are stringent as compared to Canadian guidelines.

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Summary & Conclusion

Medical devices are universal in healthcare and have potential to create large scale health gains but also have unintended harms through device failure. Medical device regulation is complex and evolving area. The development of medical technology is essential for improving patient care. Such devices have historically been used despite having scant scientific data to back them up. Even though many gadgets have significantly improved clinical results, not all of them are helpful, and some even have the potential to be dangerous. To end this most jurisdictions have developed regulatory bodies such as therapeutic goods administration (TGA) and health Canada that ensure the safety and effectiveness of new medical devices.

Medical devices are highly selling products all over the world as the field of technology has grown there is constant development in medical devices to increase its effectiveness which will indeed benefit the consumers. Thus, TGA regulates medical devices in Australia and health Canada regulates medical devices in Canada. They have different procedure for approval of medical devices. Clinical investigation and clinical evaluation should be carried for medical devices as it is important to determine safety and efficacy of devices there should not be compromise with the health of consumers. Clinical investigation data should be complied with supporting documents such as risk management report, Quality certificates etc. Clinical evaluation report can be prepared by clinical expert or reviewers which is appointed by the manufacturer to get approval of medical device.

When the devices are sent to market the regulatory agencies should keep watch on any suspected adverse event which can occur and can lead to serious consequences. If a problem occurs with a medical device, it may be reported to respective regulatory agencies. If the matter is serious the agencies can take regulatory actions on manufacturer and can also recall the product from market and then product can undergo investigation to determine cause of adverse event.

Labels are important on medical devices as it give information to the consumers. Labels can also have barcode which can be useful for traceability of product. Labels must include all the details about device along with instruction manual for proper use of device.

Thus, we have collectively studied various regulatory guidelines of Australia and Canada and also have differentiated points from the guidelines. Thus, study of these guidelines helps us to understand the regulatory terms such as clinical investigation, adverse event reporting etc and how the device must fulfil all these requirements before approval in the market. Thus, the study also explains us that Australia's guidelines are more precise and stricter as compared to Canada's guidelines.

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