Device Regulations of Other Countries

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1 Introduction

This chapter covers medical device regulation from several countries listed below:

1. India Medical Device regulations
2. China Medical Device regulations
3. Canada Medical Device regulations
4. New Zealand Medical Device regulations
5. Australia Medical Device regulations
6. Japan Medical Device regulations
7. Singapore Medical Device regulations
8. United Kingdom Medical Device regulations
9. European Medical Device regulations

The medical device regulations of these countries are similar in many aspects to that of the United States. However, they differ in a lot of areas as highlighted in each section.

1. **India Medical Device Regulations**

The medical device regulations came into existence in India in the year 2017 (Ministry of Health and Family Welfare Notification No. G.S.R, 78(E) dated 31 January 2017 notifies Medical Devices Rules 2017). Certain medical devices and in vitro diagnostic devices belonging to risk class B and C are included in the regulation. New devices are regularly added to this list by the Ministry of Health and Family Welfare. Since India imports most of its medical devices, the CDSCO (Central Drugs Standard Control Organization) has Central Licensing Authority (CLA) and State Licensing Authority (SLA) which are responsible for licensing to

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import, manufacture for sale or for distribution and sale, stock, exhibit, or offer for sale. CLA does licensing for all import devices and Class C and Class D medical devices manufacturing, loan, and wholesale licenses. CLA may take services of a notified body to examine the manufacturing site of Class C and Class D medical devices and technical review. SLA is responsible for the manufacturing, loan, and wholesale licenses of Class A and Class B medical devices. SLA selects and authorizes a notified body to validate the requirements of quality management system and technical review for Class A and Class B medical device manufacturers.

Regulated imported medical devices that have obtained prior approval in the United States, the European Union (EU), Canada, Japan, or Australia may legally be sold in India by obtaining the necessary license which would cause a limited conformity assessment process. In such cases, the applications should accompany all documentation used in support of prior approvals. It is advised to foreign manufacturers that they must appoint an importer, holding a valid wholesale license, and would also submit a device registration application and dossier to the CLA.

1.1 Steps to Import Medical Devices in India

In order to import medical devices in India, first, the device is assigned a risk class (A, low risk; B, low–moderate high risk; C, moderate high risk; D, high risk). Then, an application of licensing needs to be filed through the online portal of Ministry of Health and Family Welfare (SUGAM). After this, the CLA may schedule an inspection of the manufacturing site. If the device under consideration has a prior approval from countries like the United States, Canada, Japan, EU, and Australia, then the license is granted. However, if that is not the case, then class A and B devices are evaluated for their safety and performance based on the published data or the clinical investigation that was carried out in the respective country. For class C and D devices, the same is established by conducting clinical investigation by India itself before the granting of license.

1.2 Steps to Manufacture Medical Devices for Sale or for Distribution

The first few steps until filing an application are same as above. Once the applications are received, they are examined by the SLA or CLA already defined. The SLA can provide the license to the applicant and then schedule for a technical review and onsite audit or vice versa. The CLA however will always grant the license after the technical review and onsite audit.

2 China Medical Device Regulations

The medical device regulations in China are controlled by NMPA (National Medical Products Administration) formally known as the China Food and Drug Administration (CFDA). It classifies devices in risk categories, I, II, and III, ranging from low to high. China follows the following criteria to classify medical devices into the abovementioned three classes:

- Class I: those devices whose safety and effectiveness can be ensured through routine administration.
- Class II: the devices which would need additional control to establish their safety and effectiveness.
- Class III: these include devices which are used for life support and/or implanted into the body and therefore may be a major threat to patient's health.

In order to register medical devices in China, which are not manufactured in the country, the respective company has to provide device samples to NMPA. In the case of class II and III devices, it is mandatory for the manufacturer to send applicable documents stating that the device has been approved in its manufacturing country. Examples of such documents include CE Mark, 510(k) letter, ISO 13485 certification, approved Premarket Approval Application, etc. The application may also require providing supporting clinical data associated with the device. All the product information on the packaging label of the device should be translated to simplified Chinese. Once approved, the medical device registration in China is valid for 5 years (as opposed to 4 years). For renewal of registration, the renewal application should be submitted to the same department 6 months prior to the expiration of previous application. It is required by the outside manufacturers to hire China-based agents to represent their interests. Such agents would be responsible for proving technical service, maintenance support for the device, recall assistance, supervising the registration process, and providing support for the manufacturer in the case of an adverse event of device malfunction. The manufacturer will provide all their details (name, address, contact information, etc.) to the designated agent in the registration application.

In the year 2017, NMPA amended the medical device regulations, and in 2018, a revised draft was published. Some significant changes are outlined below:

- Unique Data Identification (UDI): The purpose of UDI is to monitor the medical devices by allowing their tracking from the manufacturing point to their distribution and use. The information to be stored in the UDI database includes the expiry and production dates of the device, the device model, and the UDI code.
- Market Authorization Holder (MAH): The MAH has to ensure the quality of their products and that they meet all applicable requirements, submit yearly self-inspection reports to respective authorities, and regularly update their products' information in the NMPA's UDI.
- Clinical Trial Management System: The clinical evaluation is not mandatory for class I and most class II devices. In order for class III devices to skip the clinical

evaluation, they should have a proven safety record. The NMPA would review the clinical data from foreign countries. All high-risk devices and devices for life support would have to be evaluated in China.
- Prioritization of innovative devices: Foreign manufacturers would be allowed to import "innovative" medical devices into China without any approval certificates.

3 Canada Medical Device Regulations

The Medical Device Regulations of Canada apply to sale, advertising and import of a medical device for sale to the general public as opposed to personal use. These regulations also apply on in vitro diagnostic products (could be a drug or contains a drug). The Canada medical device regulations also classify the devices according to risk levels. Class I is the lowest risk, and class IV is the highest risk. It should be noted that a device could be classified into more than one class; in this case, the highest classification would apply.

3.1 General

It is the manufacturer's responsibility to ensure that the medical device meets all the relevant requirements.

Safety and effectiveness requirement: The manufacturer has to identify all the inherent risks of the device, eliminate them if possible or reduce them to an acceptable level, and provide protection guidelines from those risks. The manufacturer has to also provide the information about the remaining risks with the device. The manufacturer has to minimize the hazard arising from potential failures of the device during its usage. The characteristic and performance of the medical device should not decrease under regular use such that the health and safety of the patient are compromised. The transport and storage conditions of the device should not adversely affect the medical device. The materials used in the device should complement each other so that it does not pose a risk to the patient. The design, manufacture, and packaging of the device should minimize any hazards like flammability, contamination, radiation, leakage, and electric hazards. If a medical device is supposed to be sterile, then they should be manufactured in sterile conditions and sterilized by a validated method. A measuring device should function within the tolerance limits suitable for the medical conditions and other intended purposes. For software-based devices, software would be designed keeping the intended performance in mind and validated regularly.

Labeling Requirements The import and selling of a medical device is not permitted until the labeling requirements are met. The label shall contain the name of the

device, details of the manufacturer, all the identifying information, control number for high-risk devices, details about the package contents, indication of sterility, expiry date or best before date, directions for use, performance specifications, and storage conditions. All the labeling has to be legit and easily understandable to the user. In case of absence of a label in the imported device, a prior notice has to be sent to the Minister. Before selling the medical device, it should be relabeled within 3 months of importation according to these regulations. The Minister needs to be notified in writing about who is going to relabel the product in Canada. The labeling has to be done in at least two languages (English and French). Other labeling requirements are similar to those outlined in ISO 16061.

Contraceptive Devices: Advertising A condom can be sold as long as it is marketed as a device for preventing sexually transmitted diseases (STDs), and the label of the condom should specify the same. Contraceptive devices except intrauterine devices (IUDs) can be advertised publicly but may not utilize door-to-door distribution or mail as a means of advertising.

Class I Medical Devices The minister reserves the right to ask for more information in order to approve a class I medical device.

Class II, III, and IV Medical Devices

Prohibition: These devices require a license to import or sell and advertise. The advertisement has to clearly contain the warning, "may not have been licensed in accordance with the Canadian law."

Medical Devices Deemed Licensed: For a licensed system, all its parts are considered licensed for import, sale, and advertisement. In case of a test kit, all its reagents are licensed for import, sale, and advertisement. If a licensed medical device is a part of a medical device group, that group is deemed licensed for import, sale, and advertisement and vice versa.

Application for a Medical Device License: The application for license has to be submitted to the Minister in the format decided by the Minister. It would contain the name, class, and identifier of the device, manufacturer details, and establishment where the device is manufactured.

The application for class II device would have additional details like medical conditions for which the device would be used for, list of applicable standards attested by a senior official, and copy of device label, and the in vitro diagnostic device would have to be attested by a senior official that it has undergone investigational testing on human subjects representing intended users, with a copy of the quality management system certificate indicating that it satisfies National Standard of Canada CAN/CSA-ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes.

The license application for class III devices would additionally include list of countries other than Canada where the device has been sold with all the details of the sale (units sold, problems during sale, etc.), risk assessment, quality plan, details

of the materials used in the device, the manufacturing process, a list of validation studies (preclinical and clinical, process validation, software validation, etc.), evidence of the biological safety of the device, bibliography of all the reports about the use, and safety and effectiveness of the device.

Quality Management System Certificate: This would be taken care of by an appropriately qualified person appointed by the Minister. This certificate is valid for 3 years at most. The Minister has to be notified in writing by the registrar about suspending or cancelling a certificate. Also he will notify the Minister within 15 days of expiration if the certificate is not renewed. The Minister reserved the right to fire or reinstate the registrar under certain conditions.

Foreign Manufacturers: If the foreign manufacturer were from a country that has a regulatory authority recognized by the minister, then this would allow for exemption in the submission of abovementioned documents. The application needs to contain a certificate of compliance and a summary report issued by the regulatory body of that country. The Minister can recognize a regulatory authority of a foreign country if it is able to establish that the device meets all the applicable requirements. The Minister can also provide the list of recognized regulatory authorities of foreign countries upon request.

Application for a Medical Device License Amendment: The Minister would approve any amendments like:

(a) A significant change in the application for class III or IV device
(b) A change that would influence the class of device
(c) Change in manufacturer's name
(d) Change in name of device
(e) Change in the device identifier
(f) Changes in the medical conditions, purposes or uses, or selling criteria of a class II device

Additional Information and Samples: The minister may request for additional documentation if he is not able to reach a decision about the application. This additional information may also be requesting device samples.

Issuance: If the application meets all the requirements, the Minister shall issue a medical device license or amend the license of the manufacture. The license holder would then have to comply with the terms and conditions of the license.

Refusal to Issue: If the applicant does not comply with the regulations or supplied false information, it may lead to refusal of a medical device license or amendment. The Minister shall inform the applicant in writing and provide an applicant with an opportunity to be heard.

Suspension: The following conditions would lead to suspension of the device license: any contradiction of the regulations, supplying misleading information in the application, failure to comply with the terms and conditions of the license, failure to provide the extra information/materials requested by the Minister, cessation of meeting requirements, and any future information obtained after the granting of license in terms of quality, manufacturing, etc. The Minister would

consider the licensee's history of compliance with the regulations and risk that would be caused if the license were continued. The minister shall wait to suspend the license until he informs the licensee in writing the reason of suspension and any corrective measures that may be required with the time limit. The licensee would be given an opportunity to be heard. However, if the risk were big such that patients and people using the device would be at a health risk, then the licensee would not be heard. The licensee holds the rights to appeal a reconsideration of suspension to the Minister in writing. The Minister will then have 45 days for hearing the licensee. The minister may reinstate the license if the corrective measures have been taken or the basis of suspension is unjustified.

Obligation to Inform: The license holder shall inform the Minister in an authorized form, before November 1, that all documents supplied by the manufacturer are still valid or have changed since last time. Failure to do this may result in suspension. If the licensee decides to discontinue the sale of the device in Canada, then he has to inform the Minister within 30 days of discontinuation, and the license would be cancelled.

Obligation to submit certificate: The manufacturer has to submit a copy of new or modified quality management system certificate to the Minister within 30 days of issuance.

Disclosure of Information in Respect of Clinical Studies or Investigational Testing: This is in regard to the application for class III or IV medical devices. The details of the clinical study or investigational testing have to be disclosed if the Minister issues a license under conditions discussed under "issuance." However, if this information was provided as a supporting material or contains methods exclusive to the manufacturer, then they need not be revealed. The Minister can divulge this information without the consent of the manufacturer.

Establishment License

Prohibition: Nobody can import or sell a medical device without an establishment license. This does not apply to a retailer; healthcare facility; manufacturer of a class II, III, or IV device; and a class I device manufacturer if he imports or distributes the device through someone with an establishment license.

Application: The application for the establishment license would be submitted to the Minister and contain the name and address of the establishment, details of the establishment, if the establishment is for importation or distribution, manufacturer details, medical specifications of the device, classes of the device, attestation by a senior official of the establishment that their establishment has procedures in place for distribution records, complaint holding, recalls, problem reporting, handling, storage, delivery, installation, corrective action, and servicing. The address of each building where the above procedures are carried out would also be included.

Issuance: The license would be issued by the Minister if he determines that all application requirements are met.

Annual Review of License: The review of the licenser would be submitted before April 1 every year and include all the documents in application. The review

application would be evaluated by the Minister based on the information provided.

Refusal: In an event of incorrect information or other reasonable grounds that may pose a risk to the safety of the users, the Minister would refuse to issue the license. The Minister has to notify the applicant in writing and give him the opportunity to be heard.

Suspension: The suspension requirements for establishment license are the same as for device license.

Cancellation: If the license has remained suspended for 12 months or the licensee has failed to submit a review application, then their license is subjected to cancellation.

3.2 Distribution Records

The manufacturer, importer, and distributer of a medical device would maintain distribution records for each device. Retailers and healthcare facilities may not have to maintain such records. The distribution record will contain enough information to permit complete and quick withdrawal of the medical device from the market. In the case of implants, the distribution records shall contain the information on the implant registration cards. The manufacturer would regularly update this information as per healthcare facility or the patient. The manufacturer, importer, and distributer have to retain this information for the useful life of the device and 2 years after the shipping of device. These records would be maintained in a way that they can be retrieved timely.

3.3 Complaint Handling

The manufacturer, importer, and distributer would maintain records of any reported problems regarding safety and device performance, consumer complaints, and actions taken by the manufacturer, importer, and distributer to these problems. Retailers and healthcare facilities are exempted from this as well. The manufacturer, importer, and distributer would establish and document procedures that would lead to an effective and timely investigation of the problem as well as recall of the device if needed.

3.4 Mandatory Problem Reporting

The manufacturer would make a preliminary report and a final report for the Minister, for any incident that is sold in Canada. This would include failure of the device or a decrease in its effectiveness, faulty labeling, incomplete information, etc. If this incompetence has led to the death or serious injury to the user, then this would also be reported. The preliminary report is submitted within 10 days of a serious incident and within 30 days of a minor incident. It would contain all the information about the device indicated in earlier sections, the manufacturer details, and the importer details if applicable. The date the incident was reported, details associated with the incident, contact information of the person who reported the incident, identity of the device in question, and a statement indicating whether a similar report has been made to the Minister before with details should also be included.

The final report would contain description of the incident, number of people who experienced deleterious effects to their health or have died, an elaborate explanation of the cause of incident and actions that were taken toward the incident with proper justification, actions taken after the investigation of the incident like increased post-market surveillance, corrective and preventive action with respect to the design and manufacture of the device, and device recall. The importer can submit the reports on behalf of the manufacturer with his consent. Their reports however should be identical, and the Minister should be informed about this arrangement.

3.5 Recall

The Minister shall be given the following information before any recall: details of the device (name, identifier, etc.); contact of the manufacturer, importer, and the establishment; reason for recall and associated details; assessment of the associated risk with the reported problems; the number of affected units (totaling those manufactured, imported, and sold in Canada); time period during which the affected units were circulated in Canada; name of the people to whom the device was sold; copy of recall communication; strategy planned for conducting the recall (beginning date, procedure for keeping the Minister up to date on the progress); action to prevent the recurrence of the problem; and contact information of the representative (of the manufacturer or the importer) that would answer to all recall-related questions.

The manufacturer and importer of the device would report to the Minister after the completion of recall with the results and action taken to prevent the problem from occurring again. The importer can do the submission on the manufacturer's behalf as long as they are identical and would inform the Minister of the same.

3.6 Implant Registration

The manufacturer shall provide tow implant registration cards with the implant that would contain the details of the manufacturer and the person designated by the manufacturer for collecting implant registration information; a notice informing the patient that the purpose of the card is to allow the manufacture to advise the patient of new information regarding safety, effectiveness, or performance of the implant and any corrective action required; and statement telling the patient to notify the manufacturer of an address change. An implant registration card would contain the following information: device details, details of the healthcare professional who did the implant procedure, date the device was implanted, details of the healthcare facility, and patient details. The card would be printed in both official languages and can be a total of four (two in each language). The staff member of the healthcare facility shall fill out the card immediately after the procedure and give one card to the patient and the other to the manufacturer. Patient's personal details would not be entered on the card forwarded to the manufacturer without consent of the patient or unless required by law. The manufacturer can ask the minister in writing to use an alternative method for device registration other than the cards described above. If the Minister feels that the alternate method can achieve the same goals as the cards then he can authorize this method.

3.7 Custom-Made Devices and Medical Devices to Be Imported or Sold for Special Access

Application

In this section, special access means access to medical devices that would be available for emergency use when all other traditional therapies have failed.

General

The Minister would authorize the import and sale of a class III or IV custom-made medical device for special access.

Authorization

The details of the application would include details of the device; number of requested units; manufacturer/importer details; contact of the representative; diagnosis, treatment, or prevention for which the device would be used; statement

containing the reasons why the device was chosen for the respective condition and its risk and benefits; details of the healthcare facility where the device would be used; safety and effectiveness of the device; written statement by the healthcare professional that he would inform the patient about the risks and benefits of the device; directions for use if required; and in the case of a custom-made device, "a copy of the healthcare professional's written order to the manufacturer giving the design characteristics of the device."

The Minister would authorize the device if he establishes that the benefits provided to the patients by the device outweigh the associated risks, health and safety of the patient is not compromised, there is no alternative device available in the country, and the authorization of the device would not be misused by the manufacturer or the importer to bypass the previous requirements for general devices. The issued authorization shall point out the number of units authorized for importing, number of units authorized for selling, and details of the healthcare professional to which the device would be sold.

Additional Information

The Minister may request any additional information necessary for authorization or even after authorization. The minister may cancel the authorization if he feels that the conditions for authorization are no longer being met or requested information is not submitted.

Labeling

The label of the custom-made device shall contain the name of the manufacturer and name of the device and indicate if the device is custom made or being imported or sold for special access.

Distribution Records

The manufacturer or importer is expected to maintain the distribution records of these devices in a similar manner as described before.

Reporting an Incident

The healthcare professional shall report the incident within 72 h of its occurrence with the same regulations described above.

Implant Registration

Same rules apply as above for the registration of special access devices.

3.8 Medical Devices for Investigational Testing Involving Human Subjects

General

A manufacturer or importer may sell the device (class II, III, or IV) to a qualified investigator to carry out investigational testing if the manufacturer or importers have an issued authorization and have records containing the necessary information described below.

Records

The records would contain the following information: details of the manufacturer and importer, device details, materials used in its manufacture and packaging, features of the device that allow it to be used for the respective medical condition, list of countries other than Canada where the device has been sold and the details of the sale, risk assessment and the risk reduction measures taken during the investigational testing, names of potential investigators to whom the device would be sold, institutional details where the testing would be conducted, protocol of the testing with details about device units required, hypothesis of the study, time period of the study, the patient consent form, copy of device label, and a written undertaking from each investigator; to conduct the investigational test by the protocol, inform the enrolled patient about any potential risks and benefits associated with the device, do not allow the use of the device by personnel other than the investigator, and report any incident that might happen during the study within 72 h of its occurrence.

Authorization

A written application would be submitted to the Minister for authorization. The Minister would issue the authorization if he feels that the device can be used for investigational testing without affecting the safety of the patients, investigational testing takes care of the best interests of enrolled patients, and that the objective of the testing would be achieved. The authorization shall specify the name of the qualified investigator to whom the device would be sold, kind of diagnosis or treatment for which the device would be sold, number of units authorized for selling, and the protocol for the authorized investigational testing.

Additional Information

The Minister may request additional information if he feels the need for it. The conditions that may prompt this request are as follows: if the testing can seriously endanger the health and safety of the patients, the testing contradicts the best interest of the patients, the objective of the testing may not be achieved, the investigator is not respecting the undertaking, and submission of false or misleading information. If there is failure of submission of the above documents or if the Minister identifies some problem with the submission, then he would notify the applicant in writing with explanation to either stop the sale of the device or cancel their authorization.

Labeling

The device label would contain the name of the manufacturer and the name of the device. The statements "investigational device" and "to be used by qualified investigators only" in English and in French would be indicated on the device. In case of IVDD (In Vitro Diagnostic Device), the statement "The performance specifications of this device have not been established" would be written in English and French.

Advertising

Only the person who is authorized for importing and selling the medical device for investigational testing can advertise it. The advertising has to clearly indicate that the device is for investigational testing purposes.

Other Requirements

Maintenance of distribution records, complaint handling, mandatory problem reporting, recalls, and implant registration requirements are the same as described above in previous sections.

4 New Zealand Medical Device Regulations

4.1 Legislation

The Medicines Act 1981 and its Regulations define the governing principles for the supply of medical devices in New Zealand. If other regulations apply on the device, then they need to be complied. The supplier has to ensure that their products comply with all the legislations.

4.2 Medicines Act 1981

It specifies the legal definitions for therapeutic purpose, medical device, and medicine. It defines the requirements for advertising and institutes the penalties for breaches of the Act. The key sections of the Act are:

- Interpretation
- Meaning of medical device
- Meaning of therapeutic purpose
- Powers of the Minister to prohibit imports, etc. of medicines
- Restrictions on the sale of medical devices
- Compliance with standards
- Medical advertisements
- Enforcement
- Miscellaneous provisions

- Interpretation: This section outlines the meaning of terms used throughout the act. These terms essentially have similar meanings to those described for the United States and other countries. It is suggested to go through the Medicines Act 1981 for further reading.
- Meaning of medical device: In this act, a medical device means any device, instrument, apparatus, appliance, or other article that is intended for use in humans for therapeutic purposes and not by any pharmacological, immunological, or metabolic means. The medical device would include a material that achieves the abovementioned goals. The medical device would also include anything that is going to be used with the device.
- Meaning of therapeutic purpose: This means the medical device should prevent, diagnose, monitor, alleviate, treat, cure, or compensate for a disease, ailment, defect, or injury. It should influence, inhibit, or modify a physiological process. The device has to test the susceptibility of person to a disease or ailment or influence, control, or prevent conception or test for pregnancy or investigate, replace, or modify parts of the human anatomy.
- Powers of the Minister to prohibit import, etc. of medicines: The Minister may prohibit the import, manufacture, packing, sale, possession, supply,

administration, or other use of medicines or medical devices by giving a notice in the *Gazette*. This prohibition may be permanent or conditional (not exceeding 1 year), but the Minister can exercise this power only once. He has to inform any concerned person in writing about his reasons of prohibition. It is an offence if a person goes against this Act.

- Restrictions on the sale of medical devices: The Director-General can deem a device to be unsafe and inform the importer or manufacturer in writing with his reasons. The importer or the manufacturer would have to satisfy the Director-General in return that the device is safe. They would have 45 days to send their reply from the date of notice. The Director-General may request for more evidence if he is not satisfied with those provided. If the Director-General has not questioned the safety of the device, then it should not be assumed that the device is safe as any new information may prompt him to do so. If there is an offence reported against more than two devices that they are of the same kind, then they would be considered the same until otherwise proven. If a seller fails to comply with the Director-General's request and sells the medical device or starts selling the medical device before receiving a positive notification from the Director-General, then the offending person is liable to imprisonment for up to 6 months or a fine of $5000.
- Compliance with standards: The medical device and all its components (materials and medicine it comes with, etc.) would need to comply with the standard. The seller has to clearly inform the purchaser if the device that he is buying is different from what the standard is defined for. The following things would deem a medical device to deviate from the standard: (a) any addition that is not permitted by the regulations, (b) the quantity of the addition is greater or more than permitted, and (c) the addition does not comply with the standard that is defined for that purpose. It is an offence to disregard the compliance of the standards.
- Medical advertisements: The advertisement of a medical device is prohibited if it conveys the opposite of what the device is intended for. Any advertisement that leaves out the name or description of the device, words required to be included by the regulation, or statement required by the law is not permitted.
- The advertisement that contains statement prohibited by the law or is either false or misleading is not permitted. The advertisement should directly state or imply that the medical device is not harmful or for addiction. The advertisement on TV has to have clear legit letters and should air for sufficient time to be read by the viewer. The advertisement would be considered misleading if it conveys the wrong purpose of the medical device, does not clearly tell the safety of the device, and adds purpose/effects to the medical device it is not designed for. It is an offence to create misleading advertisements for medical devices under this Act.
- Enforcement: The officer has similar power as in the United States or Canada to directly supervise medical devices. They can perform surprise inspections of the establishment where the device is being manufactured, examine any packages containing the device, oversee the manufacturing process, collect samples of the

device, check the related documents, seize any item, take photographs of articles and establishment, etc.
- Miscellaneous provisions: When any person other than the manufacturer requests for a sample of the device, they would need to put in a written request, specify the purpose of analysis, and pay the cost of the sample. Then an officer would submit it for analysis unless he believes that request is false or a hoax.

5 Australia Medical Device Regulations

The Australian Therapeutic Goods Administration (TGA) is the regulatory authority in Australia, which takes care of the therapeutic goods regulations in the country. Medical devices are categorized under therapeutic goods in this country and follow the Therapeutic Goods (Medical Devices) Regulations 2002. These regulations are similar to any other country that we have discussed in this chapter. Therefore, here, we would discuss the Australian Regulatory Guidelines for Medical Devices (ARGMD). These regulations are currently under review by the Australian government, so the version discussed here is soon to be superseded by the new one. The ARGMD gives information about the import, export, and supply of medical devices within Australia. It also describes the legislative requirements that control medical devices.

5.1 The Regulation of Medical Devices

There were approximately 36000 entries of medical devices in the Australian Register of Therapeutic Goods (ARTG) on July 1, 2011, but today, it may contain around 1 million devices. The TGA takes a risk-based approach toward regulating medical devices. The amount of regulation depends on the "intended purpose" of the device; amount of risk associated with the device in regard to the patient, the user, and other surrounding people; and internal or external use of the device and the period of use.

5.2 The Medical Device Classification System

Medical device classifications	Examples
Class I	Elastic bandages, tongue depressors, cervical collard, slings, nonsterile dressings
Class IIa	X-ray films, intravenous tubing, contact lenses, catheters
Class IIb	Blood bags, dressings for severe wounds, condoms

Medical device classifications	Examples
Class III	Coronary artery probes, intrauterine contraceptive devices, medical devices that contain medicines, such as dressings with an antimicrobial agent
Active implantable medical devices	Pacemakers, cochlear implants

5.3 Conformity Assessment and ARTG Inclusion

For ARTG inclusion, the manufacturer may use different conformity assessment procedures according to the risk classification of a device in order to show the safety, quality, and performance of a device. All devices have to go through conformity assessment except the nonsterile class I devices and those without a measuring function. However, the lower-risk devices face regulation after ARTG inclusion as opposed to higher-risk devices, which are subjected to extensive regulation before ARTG inclusion.

5.4 Medical Device Inclusion Process

The medical device inclusion process has the following steps:

Step 1 – Identify if the product needs ARTG inclusion.
Step 2 – Examine certain things before application.

- Kind of medical device, including IVD (In Vitro Diagnostics) medical device
- Manufacturer evidence for a medical device or IVD medical device
- Classification of medical device or IVD medical device
- Priority review designation
- Supporting documentation for inclusion of a medical device or IVD medical device, in the ARTG
- Auditing of applications for ARTG inclusion of a medical device or IVD medical device in the ARTG

Step 3 – Enter the TGA Business Services system (TBS).
Step 4 – Submit an application in TBS for Class I nonsterile, non-measuring, and Class 1 IVD medical devices.
Step 5 – Submit an application in TBS for Class I Medical Device (Export Only) and Class I IVD medical device (Export Only).
Step 6 – Submit an application in TBS (for all classes except Class I nonsterile, non-measuring medical device, Class 1 IVD medical device, and Class I medical device/Class I IVD medical device Export Only)
Step 7 – Processing of application

Step 8 – Printing the ARTG certificate of inclusion

5.5 Declaration of Conformity Templates (Medical Devices)

The manufacturer has to make a declaration of conformity that confirms that the device complies with the applicable provisions of the essential principles, classification rules, and relevant conformity assessment procedure. In addition, details about conformity assessment procedure and manufacture of the device should be included.

5.6 Medical Devices with Predetermined Classifications

Group A

These devices provide a secondary effect to the patient along with its main intended purpose. These devices also contain nonviable animal origin material, any materials of microbial or recombinant origin like hyaluronic acid. Some examples of such devices include wound dressings with collagen and heart valves with animal tissue leaflets.

Group B

This group includes breast implants; knee, hip, or shoulder joint replacement implants; contraceptive devices; active implantable medical devices; implantable accessories; active implantable medical devices; and active devices that are meant to control, monitor, or influence the working of an active implantable medical device.

Group C

This group contains devices like blood bags (with anticoagulant); ancillary medical devices (used in joint replacement surgery); devices meant for disinfecting, cleaning, rinsing, or hydrating contact lenses; contraceptive medical devices; and those that are non-implantable or invasive for long-term usage.

Group D

Medical devices like non-active medical devices that record X-ray diagnostic images are part of this group.

Group E

This group contains devices that would be used to clean another medical device physically, devices for export, and devices that consist of nonviable animal origin material and are designed to come in contact with the skin and are nonsterile.

5.7 Comparable Overseas Regulators for Medical Device Applications

The TGA accepts certifications from overseas regulators like the European union, US FDA, Health Canada, Medical Device Single Audit Program (MDSAP) Auditing Organization, and the Ministry of Health, Labor and Welfare and Pharmaceutical and Medical Devices Agency of Japan. The manufacturer has to follow a guidance developed by the TGA to include in their abridgement application.

5.8 Varying Entries in the ARTG: Medical Devices and IVDs

The sponsor would request the TGA to vary the entry in the ARTG if any previous information in the ARTG has changed. The variation can be requested in situations like information in the ARTG is no longer valid, manufacturer details have changed, GMDN code (Global Medical Device Nomenclature System Code) of the device has been revised, the device has a new intended purpose now, variants are added to the device, the device identifier has changed, the UPI (unique product identifier) of the device has been amended, sponsor desired to vary the list of IVD devices in the ARTG entry, etc.

5.9 Changing the Sponsor of Therapeutic Goods

The ATG needs to be informed within 3 months of the sponsor change along with the transfer assignment. The sponsor needs to submit a notification form with all the details; the ARTG entries are updated within 10 working days, and the new certificate can be downloaded after 24 h.

5.10 Clinical Evidence Guidelines: Medical Devices

This section outlines the clinical evidence guidelines for the following devices: total and partial joint prostheses, cardiovascular devices to promote patency or functional flow, implantable pulse generators, heart valve prostheses, and supportive devices – meshes, patches, and tissue adhesives. The clinical evidence is required by the Australian government to ensure the safety and performance of the device. The clinical evidence needs to remain on the register as long as the device is on the ARTG list. It may be re-requested at any time. The clinical evidence should consist of documented literature where the device has been used for its intended purpose. The risk or safety profile of the device can then be demonstrated such that all the undesirable effects and hazards associated with the device have been reduced. The classification of the device would dictate the amount of clinical evidence to be supplied along. This clinical evidence would be updated and reviewed regularly as new information based on post-market surveillance activities and as product experience become available.

5.11 ARTG Search

The ARTG register can be lawfully supplied in Australia. The Consumer Medicines Information (CMI), Product Information (PI), and public summary documents can be obtained from the ARTG. The sponsors can request cancellation of their entries into the ARTG. The secretary has to authorize these cancellations. The cancellation provisions in the Act that can be requested by the sponsor are:

- Cancellation of listed or registered therapeutic goods: section 30(1)(c)
- Cancellation of biologicals: section 32GA(1)(d)
- Cancellation of medical devices: section 41GL(d)

5.12 Regulatory Affairs Consultants

These consultants offer services like advice and assistance with the regulatory requirements. Listed are some of the industry organizations that can provide assistance with the regulatory requirements:

- ACCORD Australasia
- ARCS Australia

These are the names of the companies and they appear as it is on their website:

- Association of Therapeutic Goods Consultants Inc.
- AusBiotech

- Australian Dental Industry Association
- Australian Self-Medication Industry Association
- Complementary Medicines Australia (CMA)
- Pathology Technology Australia
- Medical Technology Association of Australia (MTAA)

5.13 Adverse Event Reporting

The sponsors would report the adverse events or the near adverse events that occur in Australia to the TGA's Incident Reporting and Investigation Scheme (IRIS). The definition of adverse event is the same in TGA as discussed in previous chapters. However, a near adverse event is an incident associated with the device that might have caused death or a serious injury if not for a timely intervention.

Exemptions to Reporting
There are eight exemption rules that can prevent the reporting of an adverse event:

1. Deficiency of a new device found by the user prior to its use, for example, if a sterile single-use device packaging is labeled with caution "do not use if package is opened or damaged" and the package seals are found opened.
2. Adverse event caused solely by patient conditions; such a condition should be preexisting or happening within the patient at the time of device use, for example, if the patient dies after dialysis because he/she had an end-stage renal disease.
3. Service life of the medical device, for example, a pacemaker loses its sensing after reaching the end of life, the elective replacement indicator has set out in due time according to the device specification.
4. Protection against a fault functioned correctly; this means that the design of the device protected against a hazardous situation. For example, an infusion pump stopped due to malfunction, and the alarm went on as intended and therefore, prevented any injury to the patient.
5. Remote likelihood of occurrence of death or serious injury, for example, a software bug is identified in a pacemaker supplied to the market, and the likelihood of occurrence of a serious injury with a particular setting is remote. Also no patients have experienced any adverse health effects.
6. Expected and foreseeable side effects that are documented in the manufacturer's instructions for use or labeling; an expected side effect that has been clearly documented in the manufacturer's submitted documents need not be reported.
7. Adverse events described in an advisory notice; if an adverse event occurs after the manufacturer issues an advisory notice, it does not need reporting.
8. Reporting exemptions granted by the TGA; the sponsor may request the TGA to exempt common and well-documented events from reporting or change it to periodic reporting on a case-by-case basis.

5.14 Process of Reporting

The following information needs to be supplied to the TGA's IRIS system in regard to an adverse event:

- Source of information and the details of the reporter
- Device identification
- ARTG number of the device
- Date of occurrence
- Elaborate description of the event
- Date of implant, if applicable
- Details of any investigations or corrective actions taken by the sponsor or manufacturer
- Information of any similar events

The report is submitted in three stages: initial report, follow-up report, and final report. The initial report would be prepared by the sponsors according to the legislative time frame, and additional information is given as it becomes available. The status of any additional investigations carried out by the manufacturer would be provided in the follow-up report. The final report would contain the things above and should be submitted within 90 days of the initial report.

5.15 Annual Charge Exemption Scheme

The Annual Charge Exemption (ACE) scheme gives a provision to exempt the annual charge for a good that is registered, listed, or included in the ARTG until it first starts generating turnover. The purpose of the scheme is to acknowledge the fact that TGA's post-market monitoring costs should only be acquired by goods that have been established into the market. This scheme allows sponsors to register their goods into the ARTG in advance before their marketing without annual charge. Once an ARTG entry begins generating turnover in Australia, the exemption ends, and the sponsor has to pay the annual charge for the respective ARTG entry each financial year till it is cancelled from the ARTG.

6 Japan Medical Device Regulations

The Pharmaceutical and Medical Device Agency (PMDA) and Ministry of Health, Labor, and Welfare (MHLW) regulate the medical devices and pharmaceuticals. They use a similar "risk-based classification system" to categorize medical device into four classes: class I being the lowest potential risk and class IV with the highest potential risk. In 2014, the Japanese Pharmaceutical Affairs Law (JPAL) was

replaced with Pharmaceutical and Medical Device Act (PMDA). The PMD covers major areas of device regulations like quality management system compliance, device registration, medical software, and third-party certifications. The manufacturers have to comply with the current PMD Act to market medical devices in Japan. There are three essential aspects to Japan's regulatory information:

(a) Classification and Product Registration

The PMDA follows the Japan Medical Device Nomenclature (JMDN) system, which is similar to US FDA's product code classification, where codes are fixed with reference to Global Medical Device Nomenclature (GMDN). These "generic names" are then classified from class I to IV depending on the potential risk associated with them. Class I devices contain the lowest potential risk as far as the patient health is concerned. Class I devices are registered through a process called "notification." All notification applications would contain a detailed device description (measurements, materials involved, etc.). Some examples include X-ray films, scalpels, and in vitro diagnostic devices. Class II devices include moderately low-risk medical devices, like digestive catheter, electronic endoscopes, and dental alloys. Class II devices have to undergo "certification" that is reviewed by a Registered Certification Body (RCB). These devices may be classified as either controlled medical device (approved by PMDA) or designated controlled medical device (certified by RCB). Those devices, which cannot be certified as class II devices would have to submitted for approval as class III and class IV devices. Class III medical devices present a relatively high risk to patients if they malfunction. Such devices include dialyzers, hemodialysis equipment, mechanical ventilation apparatuses, etc. Class IV devices are the highest-risk devices that may be life-threatening under a malfunction, for example, artificial cardiac valves, pacemakers, and stent grafts. Class III and class IV medical devices are specially controlled medical devices, class III medical devices can be reviewed by either RCB or PMDA, and class IV medical devices must be reviewed by PMDA only. CE mark and FDA approval are not accepted in Japan but can definitely speed up the registration process. The device registration does not expire in Japan; however, it needs to be renewed in every 5 years. All documents submitted to the PMDA or RCB have to be translated to Japanese.

(b) Foreign Manufacturer Registration (FMR)

The foreign manufacturers have to undergo FMR in addition to product registration to market their devices in Japan. A FMR certificate is valid for 5 years and should be renewed at least 5 months before the certification expires. The Designated Marketing Authorization Holder (D-MAH) or the Marketing Authorization Holder (MAH) would first obtain a business number by submitting a business number registration form. The Japanese regulatory officials from the PMDA would then perform audits/documentary inspection. After this the D-MAH or MAH would submit the FMR application.

(c) Device Reimbursement

After the regulatory approval of a medical device, it is mandatory to submit a reimbursement request to the MHWL already defined. There are six general reimbursement categories: A1, A2, B, C1, C2, and F. A and B categories contain already categorized medical devices, and C and F categories have relatively new devices. The decision on A and B devices is issued quickly, whereas for C devices, the applicant has to wait a little longer.

7 Singapore Medical Device Regulations

The Singapore regulation is called the Singapore Health Products Act of 2007, and it demands all medical devices to be certified by an accredited Certification Assessment Body (CAB) that is registered in the Singapore Medical Device Information and Communication System (MEDICS). All devices used for treatment in hospitals and patient clinics have to be certified and distributed under an "establishment license." This regulation prohibits the usage of any device by the hospitals and clinics that are not certified, registered, or legally distributed. This ensures the quality and integrity of all medical devices throughout the distribution process.

Some high-risk medical devices may qualify for an "abridged" product evaluation if they have already been approved by one of the following regulatory bodies: US FDA, EU Notified Body, Health Canada, Australia's TGA, and Japan's MHLW. The device submitted for abridges approval must be identical to that approved by the abovementioned authorities. In addition to certification by the Health Sciences Authority (HSA), registration and licensed distribution requirements and the supply and use of medical devices in Singapore may be subject to other regulations, such as the provisions of the Private Hospitals and Medical Clinics Act and the Radiation Protection Act. Requirements may differ with respect to the type of medical device under consideration. The manufacturers also have to maintain a quality management system that meets the requirements of HAS's already defined Good Distribution Practice for Medical Devices (GDPMDS) standard, which is similar to the international standard ISO 13485.

8 United Kingdom Medical Device Regulations

Medicines and Healthcare products Regulatory Agency (MHRA) is the authority which enforces the law on medical devices in the United Kingdom. The following regulations are important for supplying medical devices in the United Kingdom or Europe:

- The Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
- The General Product Safety Regulations 2005 (SI 2005 No 1803)

These regulations fall under the Customer Protection Act from 1987 but are still used by MHRA today.

8.1 The Customer Protection Act from 1987

The MHRA can release prohibition notices to stop the supply of any goods which would be deemed unsafe or noncompliant with the regulations. They can warn the manufacture to issue warnings about devices that are unsafe. They can pass suspension notices for any device based on suspicion that safety provisions have been disobeyed. They can even forfeit orders for goods for the same reason. The MHRA can request additional information to contemplate their decision for a revoke or prohibition or to issue a warning.

8.2 The Medical Devices Regulations 2002

In this act, the MHRA can issue a compliance notice to the offenders and request the correction of noncompliance or a restriction notice to restrict the sale of a particular device or devices of a specific class or description.

8.3 The General Product Safety Regulations 2005

The manufacturer is responsible for ensuring that all the medical devices made, imported, distributed, or sold in the United Kingdom are safe for the consumers and follow the regulations set forth in regard to labeling. The GPSR requires all products to be safe in their regular and reasonable usage; therefore, all manufacturers have to demonstrate compliance with the safety regulations. To ensure this, they can take corrective action, recalls, and report safety incidents. They are also liable for their products under the Consumer Protection Act 1987 if their product causes harm or death to any of their consumers.

8.4 Failure to Comply with the Regulations

If MHRA feels that the manufacturer has committed a serious offence by not complying with these regulations or not meeting the conditions of a notice issued to them, then they may be subject to prosecution, which includes a penalty of an unlimited fine and/or imprisonment for 6 months.

8.5 Inspections

The MHRA can perform inspections of the manufacturing site at any time if they feel the need to do so. It follows the protocol in Consumer Rights Act 2015 that the MHRA can enter premises and can inspect the devices, can evaluate the manufacturing procedures and testing facilities, and can ask for business documents and detain any if required. Any information gathered in the course of an inspection will be considered confidential according to the confidentiality provisions in Article 20 of the Medical Devices Directive (93/42/EEC), article 19 of the In Vitro Diagnostic Medical Devices Directive (98/79/EEC), and article 15 of the Active Implantable Medical Devices Directive (90/385/EEC). These were included into UK legislation by the Enterprise Act 2002, which allows the release of information to third parties in certain circumstances.

8.6 Appeals Procedure

The manufacturer has the right to appeal any decision made by the MHRA through Chartered Institute of Arbitrators (CIArb). The appeal procedure would depend on the regulatory decision of the MHRA like prohibition notice (Consumer Protection Act, schedule 2, part 1), notice to warn (Consumer Protection Act, schedule 2, part 2), recall notice (General Product Safety Regulations, Regulations 15 and 17), clinical investigation notifications (Medical devices Regulations, Regulations 16 and 29), notified body designations (Medical Devices Regulations, Regulation 45), and applications for exceptional use of noncomplying devices (medical devices regulations, regulations 12, 26, and 39). Appeals against other regulatory decisions would be processed separately probably through courts. MHRA would notify the manufacturer of their regulatory decision along with their rights to appeal.

8.7 Exceptional Use of Noncomplying Devices

A manufacturer may request to supply a medical device that is noncompliant with the law if there are no options available. This is known as an “exceptional use of a non-CE marked medical device.” There are separate guidelines for such devices under Regulation 12(5) of the Medical Devices Regulations 2002. This also includes active implantable medical devices in regulation 26 and for in vitro diagnostic medical devices under regulation 39(2).

8.8 Complaints

Complaints can be made about the behavior of MHRA personnel or advice given by them (except enforcement decisions) according to complaints procedure. All MHRA compliance inspectors and investigators are obligated to conduct their inspections and investigations according to internal operating procedures.

9 European Medical Device Regulations

The European regulation comprises of rules concerned with marketing, both placing and supplying, its human use, and accessories required for such devices. These regulations are also true for any clinical investigations that are being carried out for these devices (not discussed here). Medical devices with both medical and non-medical purpose have to satisfy all the requirements associated with devices with and without the intended purpose. The regulation does not apply to in vitro medical diagnostic devices, medicinal products, human fluids, cosmetic products, transplants, and products containing live biological organisms like bacteria and virus and food mentioned in the regulation. In this chapter, only the general requirements associated with the safety and performance of the device are discussed.

9.1 General Requirements

The medical device has to deliver the performance as intended by the manufacturer and would be designed and manufactured for the same. It should be safe and effective while doing so and should not affect the clinical condition or safety of the patient or users in general. The manufacturers will supply the safety documentation along with the device, which would include not only the risk management plan but also any predicted hazards and estimated risks. The manufacturer shall employ risk control measures during the design and manufacture of the device. The manufacturer would also manage risks so that the residual risk associated with each hazard is limited to the acceptable level. For this, the manufacturer would erase or decrease the risks through safe design and manufacture. He would also take appropriate protection measures like alarms and provide safety information and user manual. In case of user error-related risks, the manufacturer shall reduce the risks related to the ergonomic features of the device and the usage environment and provide training for use wherever possible. The packaging of the device would be designed to prevent it from damage during transport and storage.

9.2 Requirements Regarding Design and Manufacture

The materials used to design the device would be chosen in regard to (a) toxicity, (b) compatibility between materials and substances and biological tissues and body fluids, (c) compatibility between different parts of the device, (d) impact of processes on material properties, (e) mechanical properties of used materials, (f) surface properties, and (g) confirmation that the device meets the defined chemical and/or physical specifications. The device would be designed and manufactured to reduce the risk imposed by substances or particles like water, degradation products, and residues. The device or part of device that will come in contact with the body directly or through body fluids will contain only 0.1 %w/w of the respective substance. This information would also be present on the label of the device. The device packaging has to be sterilized by approved methods. In case of non-sterilized devices, the cleanliness of the product has to be maintained while packed and should be sterilized before use according to manufacturer's instructions. The labeling should be clear in terms of sterile and nonsterile devices. The devices shall be designed to prevent infection and microbial contamination to patients in instances like cuts and pricks. The design of the device shall allow easy and safe handling, reduce any possible microbial leakage from the device, and prevent device contamination from any human fluids. The packaging and labeling of the devices would reflect the same. The devices that contain tissues or cells of animal origin or their nonviable derivatives would have to be subjected to appropriate veterinary controls: sourcing, processing, preservation, testing, and handling of tissues, cells, and substances of animal origin; safety in terms of viruses and other transmissible agents would be ensured by appropriate validation methods for elimination of such agents during manufacturing while maintaining the clinical benefit of the device. In order to reduce the risk imposed by medical devices that are used by laypersons, the instruction for use provided by the manufacturer should be very simple and easy to understand. Its design should ensure safety at each stage of use or after training, reduce the risk associated with usage like cuts and pricks, and finally reduce error by the user during handling.

9.3 Requirements Regarding the Information Supplied with the Device

In previous chapters and other countries' regulations, labeling has been covered in detail. The European regulation entails similar instructions regarding labeling. In brief, each device has to have a label that contains its identity, manufacturer's name, and safety and performance profile. The label would appear on the device or its packaging or both. It would contain the name of device, manufacturer's trademark, address of the manufacturer, contents of the device (biological or not), lot number/serial number, indication of clinical or nonclinical use, and in case of implants the

serial number. The device shall contain instructions of use that are easily understood by the user or the website link where they can be found. The information on the label should be relevant to the respective device and must contain a radio-frequency identification (RFID) or bar codes. The risk information like device limitations, contraindications, precautions, or warnings has to be supplied with the device. The manufacturer has to use internationally recognized symbols in the supplied information wherever possible. In places where this is not possible, the manufacturer has to define those symbols in the accompanying documentation.

9.4 Post-market Surveillance

The manufacturer shall plan, establish, document, implement, maintain, and update a post-market surveillance system that is relevant to the risk class of the product and type of device. This post-market surveillance system would be employed to gather, record, and analyze relevant data on the quality, performance, and safety of a device for its entire lifespan and to decide, implement, and monitor any preventive and corrective actions that need to be taken. Some examples are updating of benefit-risk determination and improving risk management, updating clinical evaluation, updating the summary of safety and clinical performance, etc. If during the post-market surveillance a need for preventive or corrective action arises, the manufacturer shall take appropriate measures and inform the respective authorities or notified body.

9.5 Cooperation Between Member States, Medical Device Coordination Group, Expert Laboratories, Expert Panels, and Device Registers

The Member States shall allocate the competent authority or authorities that would be responsible for the implementation of this regulation. These authorities would have the powers, resources, equipment, and knowledge necessary to carry out the tasks associated with this regulation. The names and contact of the competent authorities shall be given to the Commission which would then publish a list. The authorities shall cooperate with each other and the Commission. A medical device coordination group (MDCG) would be appointed by each member state for 3 years that can be renewed. The members of MDCG would be chosen based on their expertise and competence in medical device field and in vitro diagnostic medical devices. The MDCG would (a) establish rules for the acceptance of opinions or recommendations regarding cases of urgency, (b) assign tasks to reporting and co-reporting members, and (c) implement the regulation regarding the conflict of interests and (d) functioning of subgroups.

9.6 Confidentiality, Data Protection, Funding, and Penalties

The confidentiality of information shall be maintained which would include any personal data or commercially confidential data for the purpose of inspections, investigations, or audits. The Commission shall cover any costs associated with joint assessment activities. The penalties shall be imposed in case of infringement of the provisions of this regulation, and necessary measures would be taken for their implementation.

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