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Medical Devices Import and Export in US, Europe and Canada

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ABSTRACT

A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, *in-vitro* reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes".

INTRODUCTION:

Any medical device that is legally in the U.S. may be exported anywhere in the world without prior FDA notification or approval. Foreign firms that manufacture medical devices and/or products that emit radiation that is imported[1-3]into the United States must comply with applicable U.S. regulations before, during, and after importing into the U.S. or its territories. Below table 16 describes and compares the requirements of import and export for 510k, PMA, and IDE. In recent years, there has been strong growth in imports across Europe and imports tend to account for around 80% of the market. Most importantly, trade between the EU dominates the import market, and companies wanting to exploit the full potential of major European countries need to ensure an effective marketing and distribution network. To import a medical device to Europe, the importer has to fulfill the following obligations.[4]

Table 1: Comparison of import and export requirements of 510k, PMA, and IDE.

Requirement	510k	PMA	Investigational devices (IDE)
Import	The device should have 510k approval	The device should have PMA approval	The investigational device must be labeled & used in accordance with regulations
Export	Any legal device from the US can be exported without any prior FDA notification	Same	Same
Export of unapproved drugs			
Export under section	801(e)(1) Device is 1. In accordance with the specification of the foreign purchaser 2. Not in conflict with laws of the exported country 3. The product is labeled on outside of shipping package that it is intended for export only. 4. Not sold in the US	Apart from 801(e)(1) regulations, it must comply with the following 1. Quality system regulation 2. Not to be adulterated 3. Re-importation should not pose an imminent hazard 4. Not to be mislabeled	802(c) for tier 1 countries, where the device is exported in accordance with the laws of that country without FDA authorization For non-tier countries section801(e)(1) and 801(e)(2) criteria must be fulfilled: 1. The device is not contrary to public health and safety 2. The device has the approval of the country to which it is exported
Record Requirements	Records pertaining to 801(e)(1) should be maintained	Apart from the maintenance of records pertaining to 801(e)(1), records should also include 1. Product's trade name 2. Type of device 3. Product's model number 4. Consignee's name and address 5. Date on which product was exported 6. The quantity of	Same as that for PMA

		product exported	
Record Retention time	Time equivalent to the life of the device and in no case not less than 2 years from the date of release for commercial distribution	Same as that for 510k	Records should be maintained at least for 5 years after the date of exportation

Factors affecting the regulations[1]

Factors affecting the regulations and approval procedures of medical devices in the U.S are.

- Regulation of medical devices which are unpredictable, inconsistent, and non-transparent
- U.S. device regulations are slow, risk-averse, and expensive

E.g. In order to get clearance for low-risk devices, device companies had to spend $31 million, of which $24 million spent towards FDA-related expenses. With respect to higher-risk devices, device companies had to spend $94 million and $75 million of that amount spent towards FDA-related expenses.

- FDA approval process is more time consuming, more costly and less predictable

E.g. In 2004, the European Union (EU) approved applications for new medical devices technologies on average about 14.2 months sooner than the FDA. By 2010, the EU process was 46.8 months faster which means the U.S. now lags behind the Europeans by almost four years.

- No timely access to safe and effective medical devices to patients
- Some experts have suggested that current pre-marketing procedures may not be comprehensive enough and may be particularly dangerous for devices that have been cleared by the FDA on the basis of substantial similarity to an already marketed device.

Major steps to overcome the above factors.[1]

1. Implementation of the Pre-market Predictability Act (PPA) – Provisions under this to improve predictability, consistency, and accountability

- Require reviewers to provide the scientific or regulatory rationale for major decisions, and it would establish an expedited approval appellate process

- Require FDA to publish detailed review summaries for 510(k) clearance

- Added a tracking number to device submissions and require trained reviewers to handle submissions.

- Framed two Investigational Device Exemption (IDE) guidance's, IDE exemptions for early feasibility studies and FDA decisions for IDE clinical investigations to reduce the cost of review and approval process

2. Novel Device Regulatory Relief Act of 2011 – Recommends for reforming the *De novo* process to allow manufacturers proactively initiate the *De novo* process without waiting for FDA to review on the 510k application.

3. Keeping American Competitive through Harmonization Act – Harmonizing FDA requirements with those of foreign regulators would help improve the system and foster job creation.

4. Renewing Efficiency from Outside Review Management Act of 2011 – Improve the third-party review program which would decrease pre-market clearance times and conserve valuable FDA resources.

5. Humanitarian Device Reform Act of 2011 – Removing the profit limit applicable to such devices and clarifying that the 4,000 patients limit applies per year.

6. Patients Come First Act

- FDA requires PMAs from pre-amendment Class III devices or move them to Class II

- Reform of current device recall authority

7. Cultivating Scientific Expertise to Foster Innovation Act– This act fixes FDA's conflict of interest established such that agency has access to the most knowledgeable experts.

8. Food and Drug Administration Mission Reform Act– This act establishes a predictable, consistent and transparent regulatory environment, facilitating innovation and applying a risk-benefit framework into the FDA's mission.

9. Modernizing Laboratory Test Standards for Patients Act–This act clarified that the FDA does not have authority over Lab-Developed Tests and Direct-to-Consumer Tests.

10. Guidance Accountability and Transparency Act - This bill require FDA to finalize draft guidance documents by a date certain or the guidance would be deemed no longer in effect.

EUROPE

Import

In recent years, there has been strong growth in imports across Europe and imports tend to account for around 80% of the market. Most importantly, trade between the EU dominates the import market, and companies wanting to exploit the full potential of major European countries need to ensure an effective marketing and distribution network. To import a medical device to Europe, the importer has to fulfill the following obligations.[4]

Obligations of importers[5]

The importer has to make sure that the products imported must comply with the applicable Community requirements and shall ensure that the manufacturer has drawn up the technical documentation that the product bears the required conformity marking or markings and is accompanied by the required documents, and that the manufacturer has complied with the following requirements.

1. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

2. Manufacturers shall indicate their name, registered trade name or registered trademark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

a. Importers shall indicate their name, registered trade name or registered trademark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

b. Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

c. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its compliance with the requirements set out in the relevant part of the legislation.

d. Importers who consider that a product which they have placed on the market is not in conformity with the Community harmonization legislation applicable shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

e. Importers shall keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

f. Importers should be involved in market surveillance tasks carried out by national authorities and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the product concerned.

Importers shall provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Export

For medical devices, the importing country may require a certificate of free sale showing that the device meets European standards. These are issued by the Department of Health. Medical equipment that contains radioactive materials may require additional certificate.[6]

Unless there are grounds for suspecting that a device may pose a risk to public health, Member States must not "create any obstacles to the placing on the market or the putting into

service of any medical devices as defined under the Directive bearing a legitimate CE marking". This means that a CE marked device may have access to the whole of the Community market and manufacturers are not required to comply with any national schemes when exporting their devices to other countries in the EU.[7]

Certain countries do not recognize the European CE marking of conformity for medical devices and demand an export certificate instead. The certificate must be issued by the competent authority at the registered place of business of the export company, in order to obtain authorizations for the devices and authorizations to import.

E.g. Firms with a registered place of business in Switzerland that export CE-marked medical devices may order such certificates from Swissmedic.[8]

CE Marking Approval Process

The steps involved in conformity assessment steps for a class I, IIa, IIb and III devices are depicted.

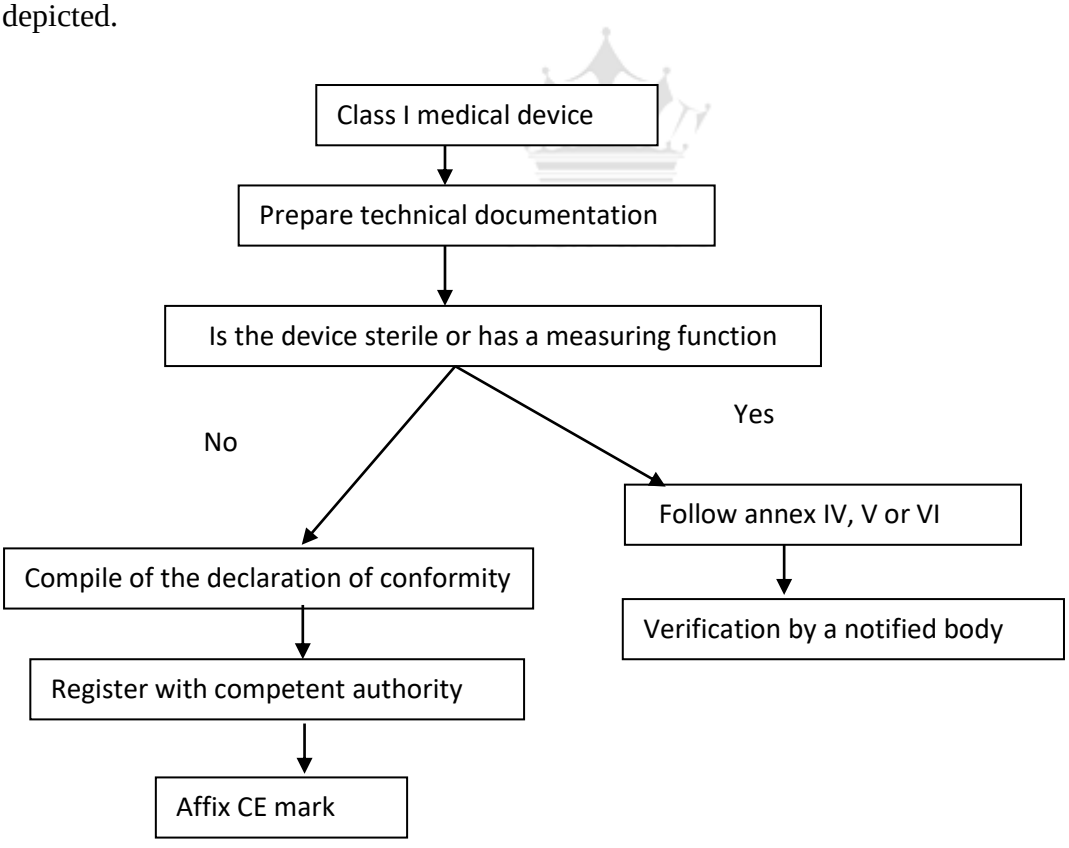

Figure 1: CE Marking Approval Process for the class I medical device

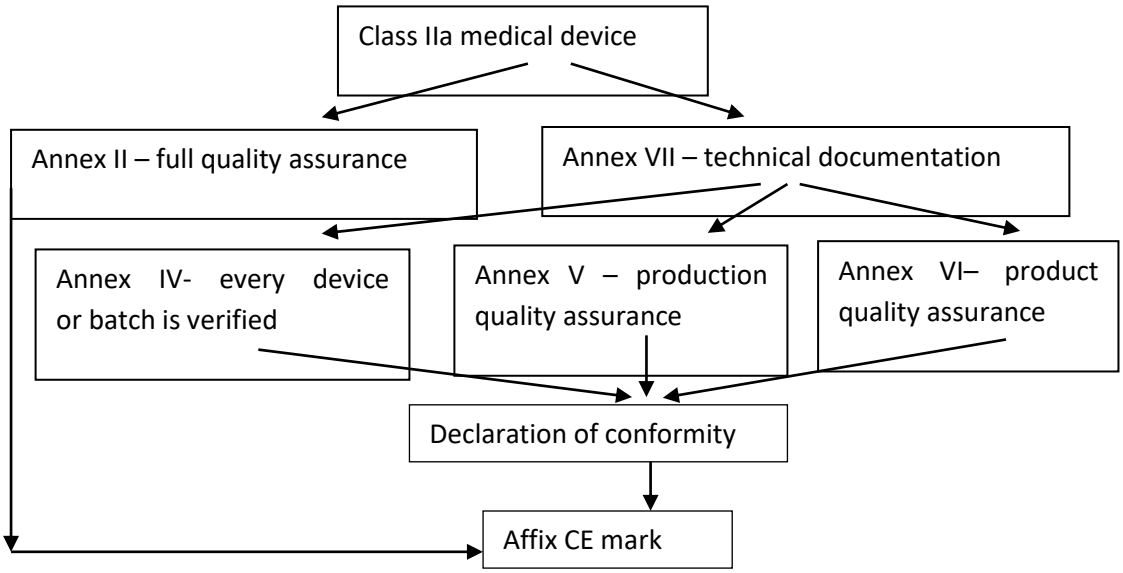

Figure 2: CE Marking Approval Process for class IIa medical device

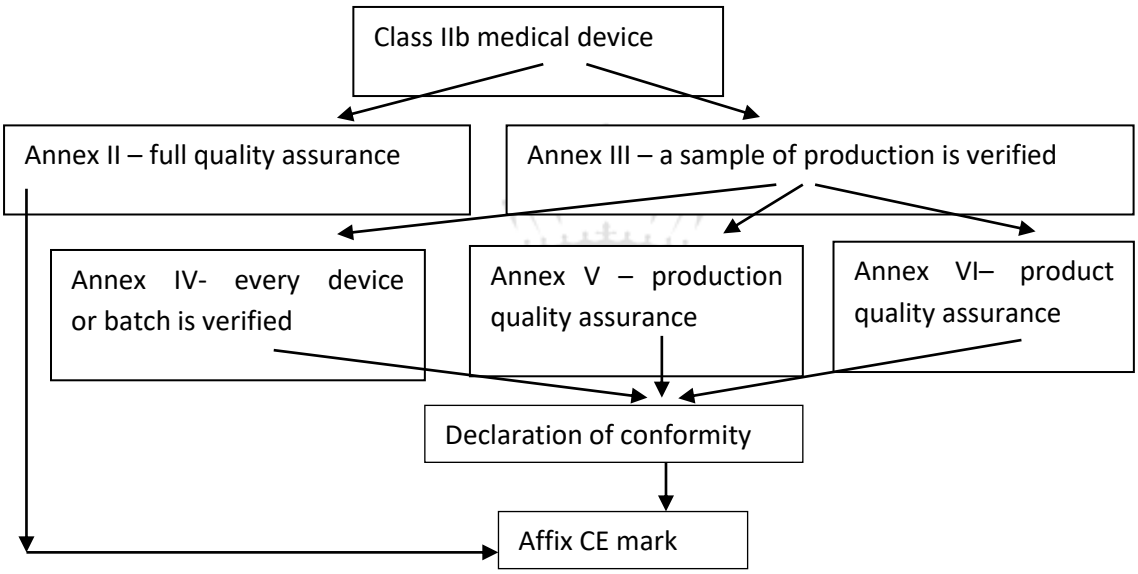

Figure 3: CE Marking Approval Process for class IIb medical device

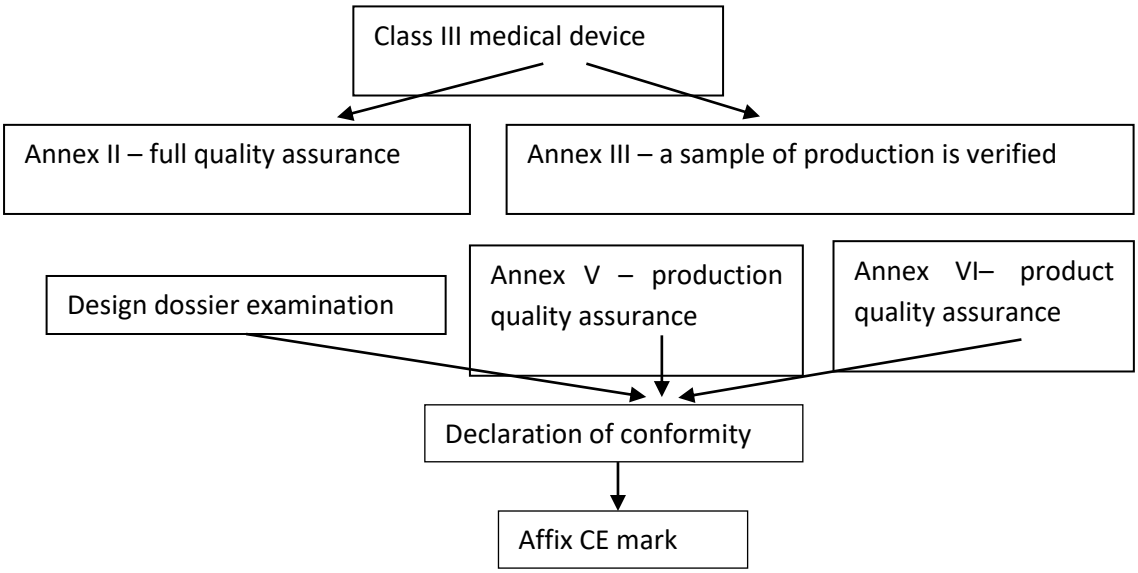

Figure 4: CE Marking Approval Process for class III medical device

In the case of sterile devices, the notified body will assess aspects of manufacture concerned with securing and maintaining sterile conditions and for devices with measuring function, they assess conformity with metrological requirements.

Import and export [9]

No person shall import or sell a Class III or IV custom-made devices or a medical device for special access unless the Minister has issued an authorization for its sale or importation.

Table 2: Import Requirements for medical device in Canada[9]

Class	Requirement
Class I	• Device License not required. • Importer must have an Establishment License
Class II, III and IV	• Device License required for each Device. • Importers must have an Establishment License
Investigational testing devices to be used on human subjects	1. Require identification as "Investigational Device" on the label of the device. 2. Letter of Authorization (LoA) issued by the Medical Device Bureau (MDB) must accompany Class II, III and IV devices under Investigational Testing status.
Custom-made devices.	3. The label must specify that the device is custom-made Letter of Authorization (LoA) issued by the Medical Device Bureau (MDB) must accompany class III and IV custom-made devices.

The following entities are exempt from the requirement of having an Establishment License (EL) to import medical devices: [10]

1. A Retailer

2. A Health Care Facility

3. Manufacturers of Class I devices if the manufacturer imports or distributes through a person who holds an Establishment License

4. A person who only imports a medical device for their own personal use

5. Establishments only importing or selling veterinary products

6. Dispensers and

7. Establishments that only import or sell custom-made devices

Table 3: Export Requirements for medical device in Canada[11]

Class	Requirement
Class I	• A Manufacturer's Certificate to Cover Export of Medical Devices is required • Manufacturer must have an medical device establishment license
Class II, III and IV	• A Manufacturer's Certificate to Cover Export of Medical Devices is required • A medical device license is required for each device

Challenges in the Medical Device Market

In spite of the vast opportunities for the medical device sector in Canada medical device faces the following challenges.[12]

Growing medical devices sector trade deficit

Canada is lagging among other developed countries in commercializing innovations into marketable products. Canada imports approximately 80-85 % of medical devices for domestic use and has an increasing trade deficit in this sector of over $2B/year.

Poor performance in export rankings

Canada also ranks poorly in comparison to other Organization for Economic Co-operation and Development (OECD) countries in the share of instrumentation exports (including medical devices).

Delayed patient access to medical devices

The ability to maintain a high-quality healthcare system is increasingly dependent on medical devices and technology. In spite of high healthcare spending relative to other OECD countries, access to medical devices and technology in Canada ranks below average.

Reasons for poor sector performance:

There are six major areas that impact Canadian performance in this sector. They are

Lack of sufficient medical devices expertise and skills

Lack of sufficient targeting of needed medical devices innovations due to extreme limitations of funding

Lack of sufficient investment

Lack of sufficient incentives to attract and retain industry

Lack of harmonization.

Lack of a national priority and or strategy for the sector

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