Market Authorization, Capitalization, Patient Access and the Forces Shaping the Medical Device Industry in USA and Europe: A Comparative Prospective

By

Palak Gupta

Dissertation submitted for the partial fulfillment of the

MBA Hospital and Health Management

Academic year, 2015-2017

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This is to certify that the dissertation titled "**Market authorization, capitalization, patient access and the forces shaping the Medical Device Industry in USA and Europe: A comparative prospective**" submitted by **Dr. Palak Gupta** Enrollment No. IIHMR-U/01/2015-17/0315 under the supervision of **Dr. S.D. Gupta** for the award of MBA in Hospital and Health Management of the University carried out during the period from 6th February 2017to 5th May 2017. This embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

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This is to certify that all ethical issues have been considered while collecting data for my dissertation titled **"Market authorization, capitalization, patient access and the forces shaping the Medical Device Industry in USA and Europe: A comparative prospective "**

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Abstract

Market authorization, capitalization, patient access and the forces shaping the Medical Device Industry in USA and Europe: A comparative prospective

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ZS Associates, Gurgaon

Guided by Dr. S.D Gupta

Keywords: medical devices, legislation, market authorization, USA, Europe, reimbursement, approval process, hospitals, FDA, regulations, medical device industry, trends

Background

The ever growing need and the inexorable urge to improve quality of life, supplemented with the will to ensure the best possible health environment for human beings, have over the years nurtured the ever intensifying interest for medical devices, broadly defined as "any instrument, implant, in vitro reagent, apparatus or similar or any related article which are used for diagnosis, prevention, or treatment of disease or any other conditions, and which does not achieve its purpose through chemical action within or on the body". More than 500,000 different types of devices in the field of healthcare are produced around the globe ranging from simple, everyday consumer products such as spectacles, dentures, to plasters and ostomy products, syringes and bandages, hip implants, MRI and X-Ray equipment, and pacemakers (Medtech Europe, 2016).

Medical device and equipment are a dynamic segment of both the USA and EU economies with the growth rate of the industry in both the regions dominating the global front with both the markets experiencing an uptick in this segment in recent years. The USA medical device industry is valued at more than $140 Billion in 2015 accounting for 45% of the global market while Europe contributes around 28% of the global market with EU-5 countries being the major shareholders constituting the major chunk of the market.

In this study medical device industry in both U.S and EU are compared on the following ground:

1. **Market Authorization and Capitalization:** Market authorization involves the entire comprehensive process from the development to the dissemination of medical devices. Marketing authorisation procedure encompasses: classification of medical devices based on some criteria, procedures for market authorization for different classes, registration of manufacturers and medical devices, marking of medical devices, time frame/period required for the completion of the entire process, post marketing requirements.
2. **Patient Access and Reimbursement process for Medical Devices:** Patient access is defined as the paying of the reimbursement money by a national or a third party payer to the manufacturers and making the medical device accessible to the patients. Reimbursement process has certain key attributes on which the comparison is made: regulatory bodies involved and the reimbursement process for medical devices in each geography.
3. **Forces shaping the Medical Device Industry:** This segment encompasses the medical device market overview in each geography, the healthcare providers landscape, the various decision makers involved in the procurement process for medical devices and the different trends dominating the market in different geographies.

Methodology
Aim

To provide a general understanding of the similarities and differences of the market authorization procedure and patient access systems for medical devices in the US and Europe under various forces shaping the industry in both the geographies.

Objectives

- To understand the medical device market with focus on the global market need, potential benefits, and drivers and barriers in medical device industry
- To examine, analyze and compare the market authorization and regulatory procedures in the USA and Europe
- To assess and differentiate medical device financing by the government and the reimbursement process involved for medical devices in the USA and Europe
- To study the emerging trends and their impact on the medical device sector in the US and Europe

Study design and tools

a) Type of study: Systematic review of literature
b) Study duration: The study is based at present i.e. the market authorization system, reimbursement process and the forces shaping the industry currently in action are studied.
c) Data collection: Publicly available secondary research data sources are deployed

Discussion and conclusion

On a broader level the market authorization procedures in both the geographies have the same basic concept. In both the systems, the endeavor to gain market authorization increases with the perceived risk of the device and in both systems an existing equivalent device on the market allows for easier market authorization. On the other hand, many striking differences between both the systems can also be identified. An important difference is that market authorization and approval process in the USA is granted and handled by the FDA, a governmental body thus, making the authorization process a governmental responsibility, while in Europe market authorization for medical devices is handled by companies and designated and supervised by the authorities and are referred to as 'Notified Bodies'. Additionally, in terms of technical requirements both the systems also differ. Although US is high on clinical investigation of the medical devices, the negative implication of this approach is that a life saving is withheld from patients in the USA who are in dire need of it, whereas the same medical device is available to the European patients.

Also, when comparing patient access and reimbursement model for both the geographies, it is shown that lower risk devices achieve market access in a comparable amount of time, the variation comes in term of the innovative and high-risk devices which require higher degree of clinical evidence and because of which the patient access time frame varies for the US and the Europe.

In term of market share and growth, U.S medical device market is pioneer globally and is expected to retain its position in the subsequent years. After U.S, Germany stands second globally with the market share of 24.5 Billions USD.

Acknowledgments

This thesis would have been an insurmountable task without the support, guidance and encouragement that I have been fortunate enough to receive from many people.

I would like to express my gratitude to my Project Manager – Mr. Deepak Sharma (Consultant at ZS) for having great vision and for patiently guiding me through this project despite his busy workload. Sincere thanks are also due to Ms. Edith Aggarwal and Ms. Malavika Kathuria, my partners on the project, for their invaluable insights and suggestions at our daily review meetings.

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Thank you.

Palak Gupta

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1.	CAP	Conformity Assessment Procedure
2.	CBER	Center for Biologics Evaluation and Research
3.	CDRH	Center for Devices and Radiological Health
4.	CE	Conformité Européenne
5.	CFR	Code of Federal Regulations
6.	CMS	Center for Medicare and Medicaid Services
7.	EC	European Community
8.	EEC	European Economic Community
9.	EU	European Union
10.	FDA	Food and Drug Administration
11.	FDAMA	Food and Drug Administration Modernization Act
12.	GAO	Government Accountability Office
13.	GDP	Gross Domestic Product
14.	GMDN	Global Medical Devices Nomenclature
15.	GPO	Group Purchasing Organization
16.	HDE	Humanitarian Device Exemption
17.	IVD	In-vitro devices
18.	MD	Medical Device
19.	MDD	Medical Device Directive
20.	MDSAP	Medical Device Single Audit Program
21.	MRI	Magnetic Resonance Imaging
22.	OECD	Organization for Economic Co-operation and Development
23.	OOP	Out of Pocket Expenses
24.	PMA	Pre Market Approval
25.	PMS	Post Market Surveillance
26.	P & R	Pricing and Reimbursement
27.	QS	Quality System
28.	SE	Substantially Equivalent
29.	U.K	United Kingdom
30.	USA	United States of America
31.	WHO	World Health Organization

1. Preamble:

Healthcare industry is one of the most composite and largest industries in the world. This industry has a very strong position in term of economy with a relatively high share of GDP of any country being contributed to this sector. Healthcare sector consists of hospitals, diagnostics and pathology, medical tourism, tele-medicine, clinical studies, research and development, health insurance and so on. Medical device industry forms an imperative and dynamic section of the global healthcare system as it plays a key role in the delivery of healthcare.

The ever growing need and the inexorable urge to improve quality of life, supplemented with the will to ensure the best possible health environment for human beings, have over the years nurtured the ever intensifying interest for medical devices, broadly defined "as any instrument, implant, in vitro reagent, apparatus or similar or any related article which are used for diagnosis, prevention, or treatment of disease or any other conditions, and which does not achieve its purpose through chemical action within or on the body." Furthermore, the remarkable scientific, technical-innovative advances occurring in the field of healthcare, have empowered the Medical Device Market across the globe with an ever amplifying number of sophisticated and inventive solutions sprouting to properly overcome and counter ailments and pathologies that were once considered to be untreatable.

More than 500,000 different types of medical devices are produced globally ranging from simple and everyday consumer products such as spectacles, dentures and sticking-plasters, to incontinence and ostomy care products, syringes and bandages, to hip implants, MRI and X-Ray equipment, and pacemakers (Medtech Europe, 2016).

Medical device and equipment are a dynamic segment of both the US and EU economies with the growth rate of the industry in both the regions dominating the global front with both the markets experiencing an uptick in this segment in recent years. The USA medical device industry is valued at more than $140 Billion in 2015 accounting for 45% of the global market while Europe contributes around 28% of the global market with EU-5 countries being the major shareholders constituting the major chunk of the market. However, medical devices investment, sanction process, regulation, reimbursement and acquisition is differently structured both in the USA and EU, with vastly different regulatory frameworks and market entry vehicles for foreign companies to navigate.

In this study Medical Device Industry in both U.S and EU are compared on the following ground:

1. **Market Authorization and Capitalization:** Market authorization process involves the entire process right from the development to dissemination of medical devices. It involves competing interests: ensuring that the medical devices under scrutiny are both safe and effective, facilitating the movement of innovative devices as rapidly as possible so that they are available to the public at the earliest.

   Balancing these objectives falls on to the Federal "Food and Drug Administration (FDA)" in the United States, and to regional and centralized regulatory bodies in the European Union who provides CE Marking to the authorized medical devices. In Europe, the regulatory framework for market authorization of medical devices consists of three main directives "90/385/EEC Active implantable medical devices, 93/42/EEC medical devices and 98/79/EC in- vitro diagnostic medical devices" while in USA there exists the Federal Food Drug and Cosmetic Act (FD&C Act) and the Food and Drug Administration Modernization Act of 1997 (FDAMA), covers the regulation of food, drugs, devices and biological products specified along with providing regulation for market authorization of medical devices.

   Marketing authorization system encompasses:

   - **Classification of Medical Devices**

     In both the US and Europe, classification systems for medical devices (based on level of risk) are used as a basis for the market authorization procedures and provide distinction between low, medium and high risk devices. Under the USA legislation, medical devices are segregated into the following categories:

     - ✓ **Class I:** Devices that are not intended to help support or sustain life and may not present an unreasonable risk of illness or injury.
     - ✓ **Class II:** These devices are designed to perform as indicated without causing injury or harm to the patient or user
     - ✓ **Class III:** These are the devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury

- ✓ **Humanitarian Device Exemption (HDE):** Device that is intended to benefit patients by treating or diagnosing a disease or condition that is termed as 'orphan'

While in Europe, medical devices are assigned to either of the four regulatory classes:

- ✓ **Class I** : Low risk medical devices
- ✓ **Class IIa** : Medium risk medical devices
- ✓ **Class IIb** : High risk medical devices
- ✓ **Class III**: Very high risk medical devices

- **Procedures for Market Authorization**

In the US, legislation concerning medical devices is governed by the FD&C Act which is implemented by regulations Title 21 Code of Federal Regulations (21 CFR) Parts 800-1299. Definition of a medical device, classification, conformity assessment and registration requirements are described in these parts. There are two main procedures requiring FDA involvement namely, Pre-market Notification or 510(k) and Pre-market Approval (PMA) .

In Europe, conformity assessment procedures are there for all the classes of medical devices carried out by different notified bodies.

- **Registration of Manufacturers and Medical Devices**

In the USA, owners or operators of medical device establishments or facilities are required to register annually with the FDA if they are engaged in the production or distribution of medical devices intended for use in the USA along with registering the list of devices they made and the activities that are performed on those devices. In Europe, according to Article 14 of the MDD, manufacturers of Class I are required to register with a Competent Authority when placing medical devices on the EU Market. Also, only manufacturers are required to register while the economic operators are exempted from any such obligation.

- **Marking of Medical Devices**

There is no official mark for FDA approved devices in the USA. However, in Europe the medical device that is legally placed in the market should bear a CE mark along with an identification number of the notified body if involved.

- **Time frame for Approval**

Time frames are given for the FDA to process Pre-Market approvals (180 days) and 510(k) approvals (90 days). However, FDA does not always abide by the given time frame.

In Europe, as such no specific procedure time is mentioned. In practice, clients can negotiate with the involved notified bodies.

- **Post-Marketing Requirements**

  In the USA, manufacturers have to report to the FDA, incidents and events that requires remedial action to be taken to prevent the risk of substantial harm to the public health. In addition, Quality System (QS) Regulation is also conducted in the post-marketing phase for medical devices.

  In Europe, the MDD requires manufacturers, irrespective of the device class, to appoint and keep up to date a systematic procedure to review experience gained from devices in the post-production phase.

2. **Patient Access and Reimbursement process for Medical Devices:** Patient access is equated with the availability of the medical device to the patients when the reimbursement money is paid by a national or a third party payer to the manufacturers. Public/private insurers decide whether and at what price they will pay for a device. Generally, public system takes longer timeframe to make reimbursement decisions as compared to their private counterpart. Reimbursement process in any region greatly depends on the type of insurance coverage availed by its inhabitants. Comparatively more Europeans have public insurance as compared to Americans.

   In US upon FDA approval CMS (Centers for Medicare and Medicaid Services) provides reimbursement for majority of medical devices. On the contrary in Europe especially in EU-5 countries, medical devices on being granted CE-mark are evaluated by the respective regulatory authorities in different countries before being reimbursed especially in the public sector. European countries usually require additional data on the device's safety and effectiveness, as well as on cost-effectiveness before granting reimbursement.

   Medical Device market in the U.S and EU-5 are compared on the following key points:

   - **Regulatory Bodies involved in the Reimbursement procedure**

     U.S and Europe differ on account of the principal regulatory bodies involved in the reimbursement process both at the national and regional level. Before being granted

reimbursement, medical devices are assessed by regulatory bodies for technical, economical and clinical evaluation.

In U.S, FDA is the primary regulatory body assisted by accessory embodiments, who together oversee the reimbursement process of medical devices.

While in Europe, each country has its own set of national and local bodies, who have the job of enlisting the medical devices on the national formulary list before allocating reimbursement under their respective national trusts.

1. **Reimbursement process for medical devices**

   Medical device journey for the reimbursement process starting from getting enlisted in the system to receiving payment is distinctive for each country and thus, greatly differs. It's a highly distinct process which varies for different medical devices depending on their specialization or the medical procedures in which they are utilized.

   In U.S, codes are granted to different medical devices on the basis of which they are reimbursed where different codes signify different payment tariffs.

   In Europe, different countries have distinctive reimbursement processes for medical devices where the payment is based on the procedures in which they are used (in-patient or out-patient setting) or the category to which the device belongs to.

3. **Forces shaping the Medical Device Industry:** Forces influencing and shaping the medical device industry varies in both the US and EU based on different consumer needs, demographics, epidemiology of diseases, provider setting landscape, emerging changes due to the dynamic administrative scenario with Trump's victory in USA and application of Brexit in EU, changing procurement process of medical devices in the provider setting and new emerging payer behavior in context with the new healthcare reforms coming.

   Comparison under this segment is done under the following heads:

   - **Medical Device Industry Market Overview**

     Current and forecasted market size of the medical device industry is compared along with analyzing the different market drivers and barriers influencing the market in both the geographies. Additionally, all the competitive conditions affecting sales and trade of medical devices in both the regions are taken into account and a comparative analysis is done based on the import and export market in both the geographical sectors.

- **Provider Setting Landscape**

  Different indices of provider setting landscape i.e. number of hospitals, beds, healthcare professionals and their trends through the years are compared to predict the requirement and utilization of the medical devices in these provider settings.
- **Procurement procedure for medical devices**

  General procurement procedure for medical devices followed in each geography keeping in account the various decision-makers involved and the amount of leverage they have in taking the final call is compared.
- **Emerging trends**

  Trends making or intended to make an effect on the medical device industry are compared to predict the ripple effect they can have on the industry in the respective geographical locations.

The way in which medical devices market is structured in US and EU differs significantly, with vastly different regulatory frameworks and market entry vehicles for foreign companies to navigate. This study is intended to provide a general understanding of the similarities and differences of the market authorization systems for medical devices in the USA and Europe.

2. Objectives

- To understand the medical device market with focus on the global market need, potential benefits, and drivers and barriers in medical device industry
- To examine, analyze and compare the market authorization and regulatory procedures in the US and Europe
- To assess and differentiate medical device financing by the government and the reimbursement process involved for the medical devices in the US and Europe
- To study the emerging trends and their impact on the medical device sector in the US and Europe

3 Materials and methods

a. Study Design

A systematic review of literature has been applied in this research to study and assess the medical device industry in the U.S and Europe and to eventually do a comparative analysis between both.

b. Study Duration

The study is based at present, i.e. authorization, market access and reimbursement models in the latest year, while for different forces shaping the medical device industry a retrospective analysis is done in order to predict the trends in the coming years.

c. Data Collection

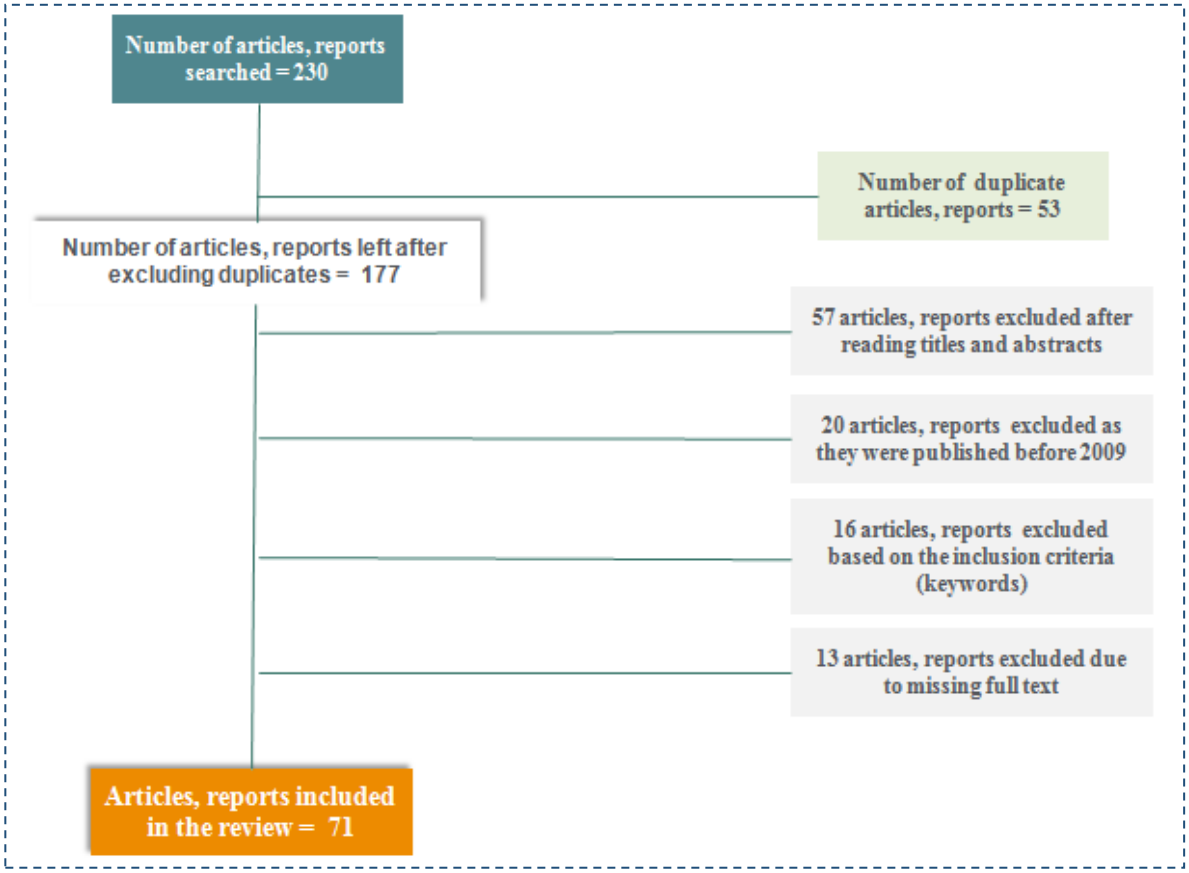
Secondary Research is conducted. The data gathered from various sources is compared and analyzed. The data are collected from:

- Internal Data such as previous researches from various published sources and written submission from interested parties was taken into account
- Government statistics and information from government agencies like WHO, OECD, Eurostat, FDA
- Different sources like articles from journals, reports from research centers and electronic databases that includes Research Gate, PubMed Central, BioMed Central, ScopeMed, Oxford Journals, British Medical Journals and International journal of health sciences and research

d. Sample

The data are obtained for two geographies namely the USA and the Europe. In Europe, only five countries constituting EU-5 i.e. Germany, France, U.K (United Kingdom), Italy and Spain are considered. The selection basis for taking these countries in the estimation is based on the good data availability for these countries as they are the leaders in the domain of medical device market. As a comparative analysis, the estimate is also based on these countries representing the European Union and the USA.

e. Sample Size



Keywords (inclusion criteria): medical devices, legislation, market authorization, USA, Europe, reimbursement, approval process, hospitals, FDA, regulations, medical device industry, trends.

Exclusion Criteria: Articles and reports on drugs and medicinal products approval and reimbursement process in the USA and Europe were excluded.

The sample size contains **71** relevant articles, journals, projects and papers published.

4 Review of literature

This study is all about finding and comparing the similarities and difference in the medical device market in terms of market authorization, capitalization, patient access, reimbursement and factors chiseling the industry of these two distinct geographies namely US and Europe Union. This literature review is all about discussing in depth the various elements on the basis of which this study has been structured and established which in turn is achieved by evaluating previous studies revolving around medical device industry and its

components. This segment of study provides through selective reference to some of the literature, a better understanding of the medical device market in both US and EU and outlines previous research findings and trends on the medical device journey in both geographies.

4.1 To understand the medical device market with focus on the global market need, potential benefits, and the drivers and barriers in the medical device industry.

4.1.1 Medical Devices

The World Health Organization (WHO) defines a "medical device as any instrument, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purposes including diagnosis, monitoring, and prevention of diseases" (WHO, 2003)[1]. Thus, any device that has an intended use for analyzing data gained from a human, changing human anatomy or analyzing substrates from a human are considered medical devices.

It is estimated that there exist over 500,000 diverse medical devices on the market, which are further categorized into 20,000 generic groups[2]. In the broad categorization, the medical device segment is divided into medical device technology and in-vitro medical devices (MedTech Europe 2015)[3]. These segments are such that the in-vitro devices (IVD) are used in analyzing human substances, while the medical device technology group includes all other devices and products.

Global Medical Devices Nomenclature (GMDN) Agency has further categorized the medical devices in 16 product group categories (MedTech Europe 2012, GMDN 2010)[4]which are enumerated in the following table:

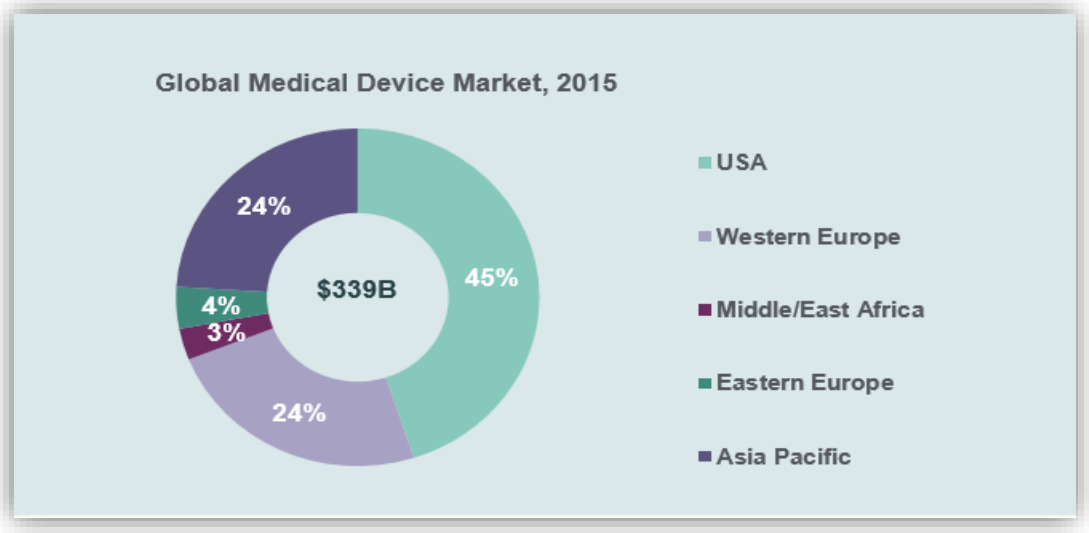
Table 4.1: Classification of Medical Devices

CODE	CLASSIFICATION	EXAMPLE PRODUCTS
01	Active implantable technology	Cardiac pacemakers, neurostimulators
02	Anesthetic and respiratory technology	Oxygen masks, anesthesia breathing units
03	Dental technology	Dentistry tools, tooth floss, tooth brushes
04	Electromechanical medical technology	X-Ray machines, CT scanners, MRIs
05	Hospital hardware	Hospital beds
06	In-vitro diagnostic technology	Pregnancy test, blood glucose strips
07	Non-active implantable technology	Cardiac stents, hip or knee replacements
08	Ophthalmic and optical technology	Spectacles, contact lenses
09	Reusable instruments	Sterilizable surgical instruments, endoscopes, stethoscopes
10	Single use technology	Syringes, needles, surgical gloves, gowns
11	Technical aids for disabled	Wheelchairs, hearing aids
12	Diagnostic and therapeutic radiation technology	Radiotherapy units
13	Complementary therapy devices	Suction cups, bio-energy mapping systems
14	Biological-derived devices	Biological heart valves
15	Healthcare facility products and adaptations	Gas delivery systems
16	Laboratory equipment	Most IVD which are not reagents

Source: GMDN

4.1.2 Medical Device Market

Medical device industry is one of the most humongous industries in healthcare, directed by innovation and new technologies. The last decade has seen an unprecedented rise in innovative and improved technologies, which has resulted in the development of state-of-the-art medical devices and has catalyzed growth and advancement in the overall healthcare industry[5].



Adapted from U.S Government Accountability Office, 2015

Figure 4.1: Global Medical Device Market geographic segmentation, 2015

The global medical device market size stands at nearly 400 billion U.S. dollars. From the figure 4.1, it is clearly indicated that the U.S. medical device industry is the global leader with sales of around $145.948 billion, which represents approximately 45% of the global market, according to the U.S. Government Accountability Office (or GAO) 2015 statistics with Europe standing second with the market share of 28% followed by Asia Pacific (24%) and Africa (3%) [6]. The global medical technology industry is expected to blossom with a compound annual growth rate of 5.7% (Statista, 2016) keeping in view the various technical innovations coming in the field of healthcare [7]

4.1.3 Drivers of Medical Device Market

Following are the drivers of the medical device market:

1. **Strong growth driven by demographic factors:** According to WHO, between 2015 and 2050, the proportion of the world's population over 60 years will nearly double from 12% to 22%, thereby making the older population over 60 years outnumber children younger than 5 years [8]. This is creating an uproar in the medical device market to create devices catering to this specific segment of the population. The ophthalmic, cardiovascular and orthopedic device markets are all getting influenced by the ageing sector.
2. **New upcoming lifestyle and chronic diseases:** The emergence of new lifestyle and chronic diseases like hypertension, diabetes mellitus, dyslipidemia,

overweight/obesity and cancer globally has created a new section of medical devices used specifically for this cause thereby, increasing the overall potential and demand of the Medical Devices in the healthcare sector.

3. **A new way of life:** With rising per capita income globally, increasing number of consumers are demanding the latest in medical treatment and services, thereby creating a demand for new, minimally invasive and self-sustained technology.

   Also, continued efforts are being exerted by the government to bring all its citizens under the basic medical coverage and modernize its health infrastructure and by health providers to improve the quality of life, which is achieved by the application of the new improved medical technology [9].
4. **Medical-technical Innovation:** Unprecedented advancement in innovative and developed technologies in the field of healthcare sector is leading to an expansion of the overall medical device industry, making it more lucrative for the companies to invest and be a stakeholder of this healthcare segment.
5. **Shifting focus on Tele-Health and Home Diagnostics products:** Increasingly ageing population has led to a shift in the medical device product mix with more emphasis on Tele-health and Home Diagnostics products.
6. **An accessible market:** Medical devices present large market opportunities, as well as a good revenue turnover for medical device startups[10].

A study conducted by Petra Maresova, et.al analysis the external and internal environment of the medical device industry. The aim of the study was to investigate the current situation in the medical device industry in Europe, its potential strengths and weaknesses in the context of economic and demographic development. The study specified an analysis of the economic state of the MD industry in the context of demographic development of European Union's macroeconomic indicators and views of experts in the field of medical device development, concerning the opportunities for entities involved in the medical device market. It concluded that the innovative activity is stable and well regulated by responsible authorities in Europe. Worldwide, the medical device market is expected to grow. As far as its future development is concerned, the medical device industry may look for new opportunities for its development in the developed economies, the expanding middle class in the emerging nations and in aging population [11].

4.1.4 Barriers in Medical Device Market

Following are the barriers existing in the medical device market who pose a threat to the manufacturers trying to enter the domain[12, 13]

1. **Stringent regulatory environment:** Stricter regulatory environment for medical device approval process, including the Affordable Care Act's excise tax, longer FDA review, and tightening rules in Europe for CE Mark approval all create challenges for the manufacturers.
2. **Hiked competition:** Adding to margin pressures is increased competition through greater globalization and venturing of companies in foreign regions.
3. **Emergence of Group Purchasing Organizations (GPO):** Development of GPOs across the globe has effectively limited the pool of potential customers for the medical device companies.
4. **Application of cost-containment measures:** Trends related to cost-containment initiatives such as lower reimbursement from government programs and increased awareness and cost sensitivity of patients and their healthcare providers.

4.2 To examine, analyze and compare the market authorization and regulatory procedures in the USA and EU-5

4.2.1 Overview of U.S. and EU Medical device market

Medical device market in U.S. and EU form the backbone of the global market with both of the geographies contributing the maximum in terms of production and consumption of medical devices along with being leaders in the development of innovative and improved products. This market is a dynamic segment of both U.S. and EU economies with the growth rate of the industry in both the regions dominating the global front with both the markets experiencing an uptick in this segment in recent years. The USA medical device market is valued at more than $140 Billion in 2015 accounting for 45%[14] of the global market while Europe contributes around 28% of the global market with EU-5 countries being the major shareholders constituting the major chunk of the market. The 40 major companies that account for almost 90 % of the medical device industry market turnover are based in the USA and Europe with Johnson&Johnson, Medtronic and GE Healthcare as the pioneer companies in the USA and Siemens Healthcare and Philips Healthcare in Europe.

However, medical device investment, sanction process, regulation, reimbursement and acquisition are differently structured both in the USA and EU, with vastly different regulatory frameworks and market entry vehicles for any company to navigate.

Thus, one of the major issues for companies operating or planning to operate in these two regions is to be updated on the regulatory requirements and implement them in the process, to understand the reimbursement process under which their respective device could be covered and to grasp the ongoing trends which will help them in better positioning their product.

4.2.2 Market Authorization and Capitalization

A. Current medical device approval process

According to the WHO, "each nation itself is responsible for placing policies and regulations that address all elements regarding the development and distribution of medical devices. The main elements of the medical product life cycle include: high quality and good manufacturing practices, affordable prices with safe, appropriate use all the way to safe disposal after the use" (WHO 2013). [15]

For medical devices, market authorization involves regulation of the development and dissemination of medical devices. It involves competing interests namely: ensuring that the devices under scrutiny are both safe and effective, facilitating the movement of innovative devices as rapidly as possible so that they are available to the public at the earliest.

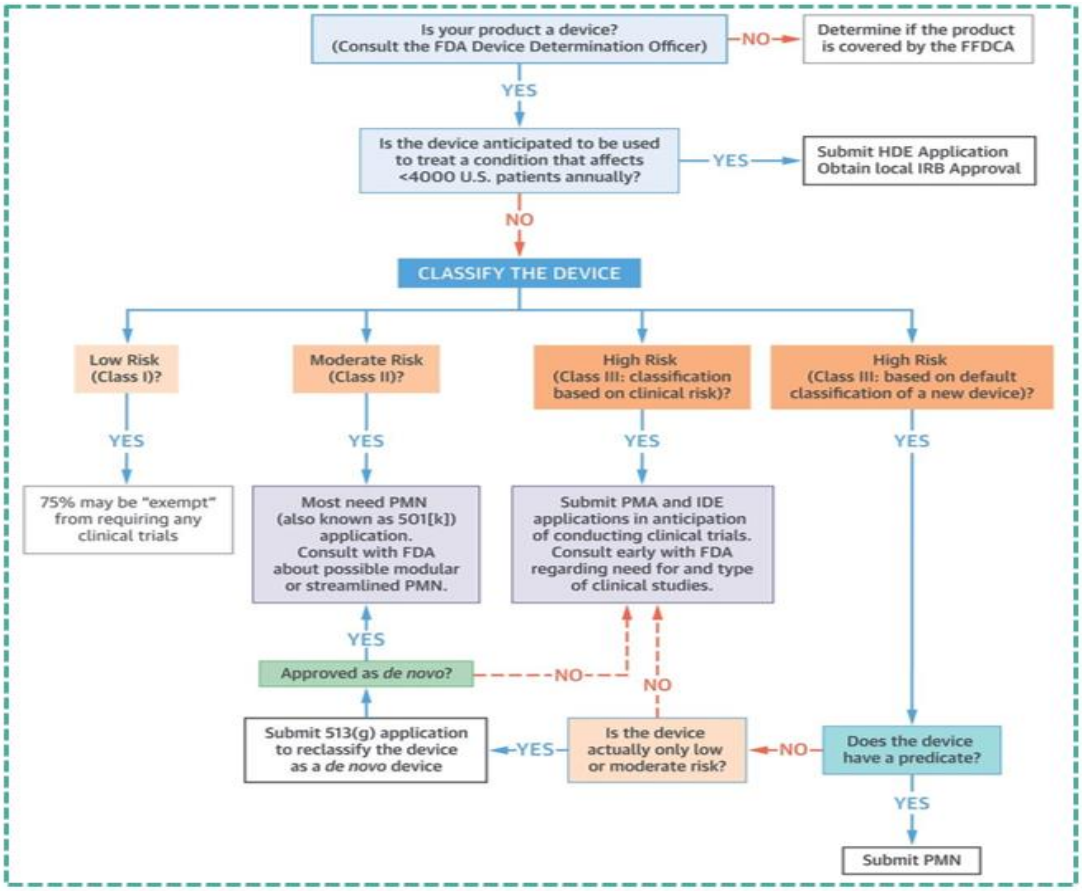
Balancing these objectives falls on to the Federal Food and Drug Administration (FDA) in the United States, and to regional and centralized regulatory bodies in the European Union who provides CE Marking to the authorized medical devices. In Europe, the regulatory framework for the market authorization of medical devices consists of three main directives "90/385/EEC active implantable medical devices[16], 93/42/EEC medical devices[17] and 98/79/EC in- vitro diagnostic medical devices[18]". These directives are supplemented by a number of amending or implementing Directives, Commission Regulations and several other legal reference documents, medical devices must be in conformity with the rules established by these directives prior to being marketed and/or put into service in the EU. At the EU level, there is no centralized approach to authorize medical devices similar to that in the United States. In the USA there exists the Federal Food, Drug, and Cosmetic Act

(FD&C Act) [19] and the Food and Drug Administration Modernization Act of 1997 (FDAMA) [20] which covers the regulation of food, drugs, devices and biological products specified along with providing regulation for market authorization of medical devices.

The European Medicines Agency of the EU, unlike the Federal Drug Administration (FDA) in the United States, is not involved in the approval process of medical devices. Medical devices in the EU are assessed for efficacy and safety by, notified bodies, which are private organizations/firms staffed by experts and certified by the EU Member States[15]while in U.S everything is performed entirely by the government i.e. FDA. EU members have the authority of implementing the legislation and taking any measures required to ensure that medical devices meet the set required criteria prior to being marketed in the EU and/or put into service.

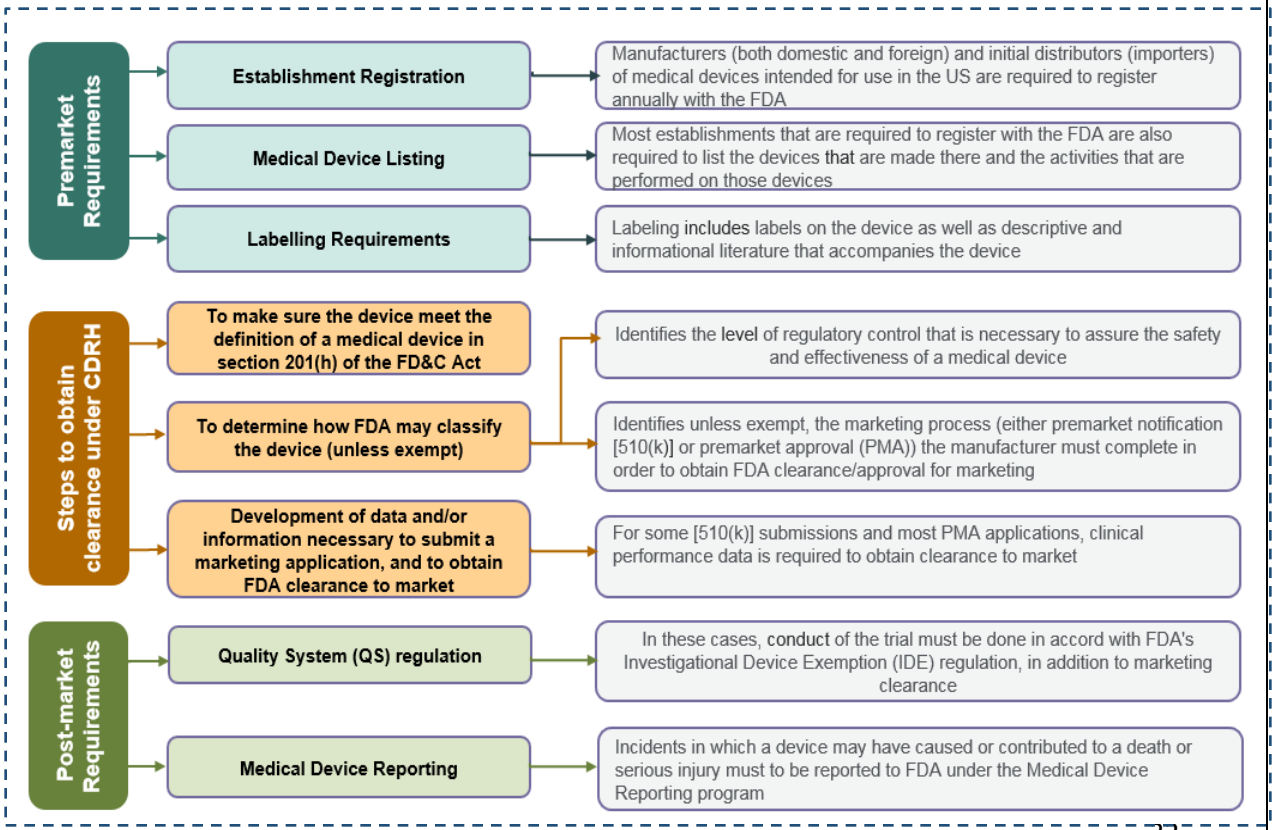
In both the U.S and Europe the authorized systems have been criticized with regard to guaranteeing the safety and effectiveness of medical devices. The critical focal point of the criticism has been on medical products, obtaining market authorization by using safety and effectiveness data of existing products on the market by claiming equivalence between them and the existing product[21]. This has resulted in the occurrence of adverse events as a result of which in the EU the Notified Bodies have been made more stringent and their supervision has been escalated.

Following is an overall view of how the medical devices undergo an approval process in the U.S under the regulation of the FDA.



Adopted from: FDA

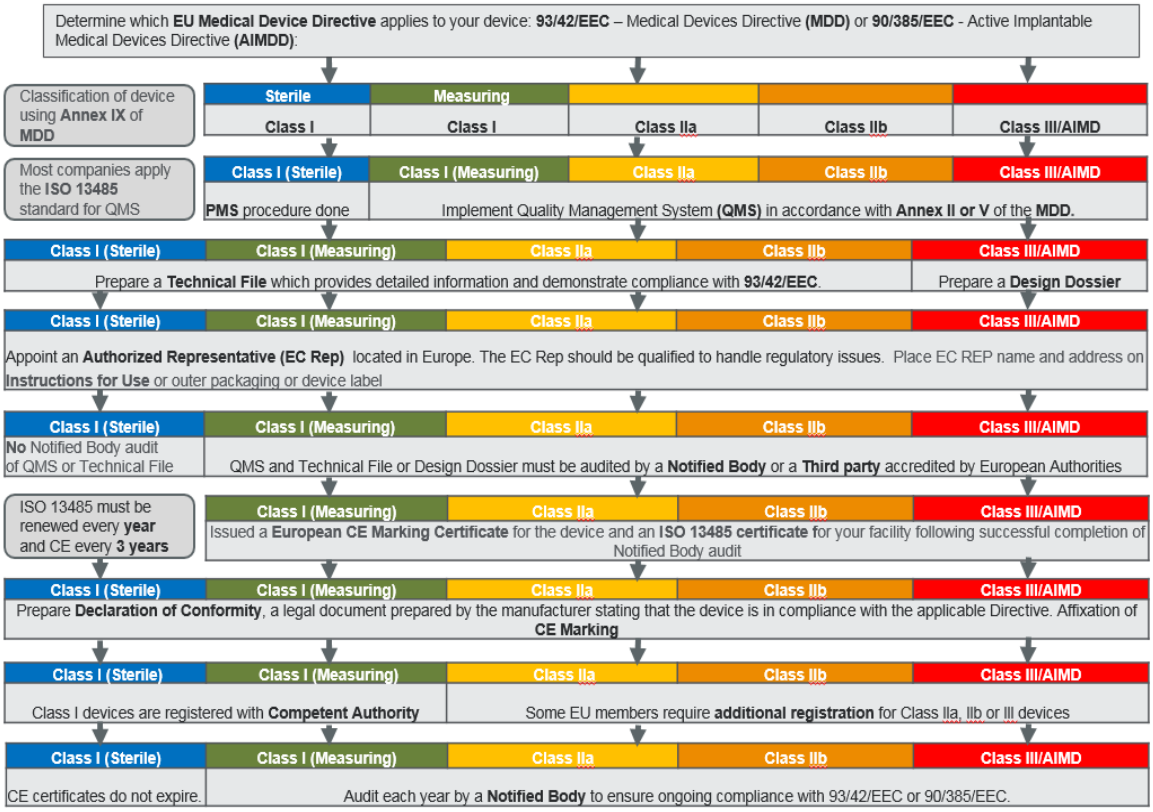
Figure 4.2: Overview of Medical Device Aprroval Process in the U.S



Adopted from: FDA

Figure 4.3: Medical Device journey in U.S market

In the EU, the set directives in conjugation with the Notified bodies grant approval for the medical devices of the following approval process.



Adopted from CE marking under EC

Figure 4.4: Flowchart of current approval process of Medical Devices in EU

B. Classification of the Medical Devices

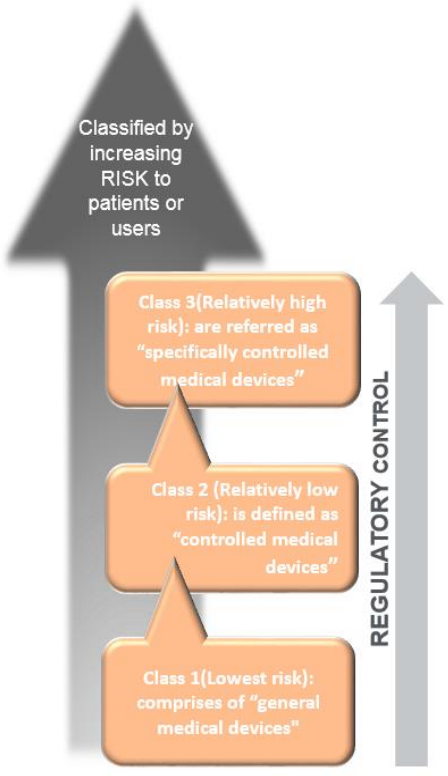
In both geographies, medical devices are classified into subsequent classes based on the "risk based" criteria where, classification system is used as a starting point for the market authorization procedures.. The medical device is classified according to the rules set by the regulatory body for device classification plays a major role in the marketing clearance application, since the final product can only be marketed according to this classification. Therefore, the basic concept of both the systems is comparable [21].

Based on the amount of risk presented, the classification of medical devices makes a distinction between low, medium and high risk devices. Classification of the device is an essential tool for it determines the (choice of) approval and market authorization procedure that has to be followed to obtain final market authorization. Therefore, the first step in the approval process is taken by the manufacturer, who is required to determine the class of its medical device in order to apply the appropriate conformity assessment rule. Most stringent

marketing approval and authorization procedures are required for high risk devices because of which the effort required to gain market authorization automatically increases for high class and decreases for products falling into the low risk class [22].

The classification rules of medical devices, depends on the vulnerability of the human body, taking into account possible dangers inherent in the technical design and manufacture of the devices. Application of the classification rules is based on the intended purpose of the devices. Most devices fall within the classification rules, except for a small number of products that are difficult to classify, such as borderline products or those with an unusual nature.

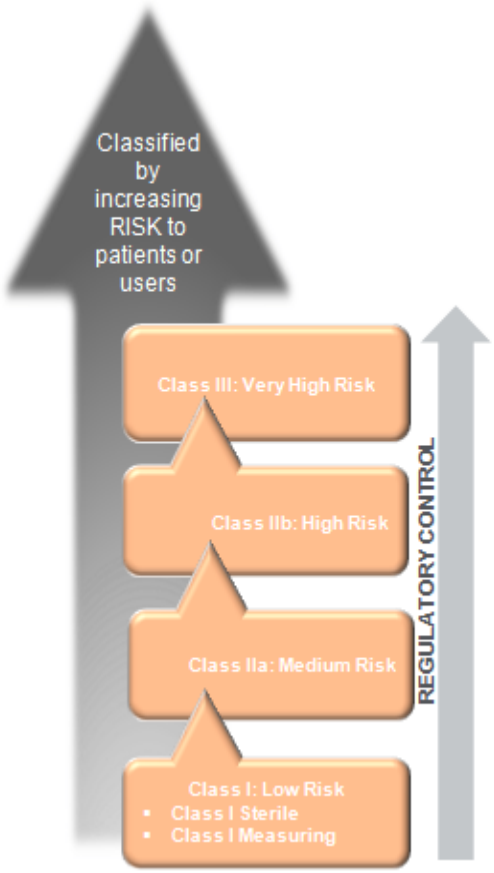
For the risk classification of the devices, detailed classification rules are available in Europe, whereas there are no detailed rules in the USA, where the classification is done by the FDA. Also, In the USA, reclassification of a device is an easier process than in Europe. Another difference is that Europe has a strict set of rules to categorize the devices in their risk classes, while the USA follows a much more diffuse approach[23].



Class of Device	Class Description	Examples
Class I	Devices that are not intended to help support or sustain life and may not present an unreasonable risk of illness or injury; Least regulated devices; marketed by submitting a notification to the Pharmaceutical and Medical Device Agency (PMDA).	Dental Floss, Adhesive tapes
Class II	These are designed to perform as indicated without causing injury or harm to patient or user; Subject to safety and effectiveness study through Pre-market Notification (PMN)	Acupuncture needles, infusion pumps, surgical drapes
Class III	These are the devices that support or sustain human life, are of substantial importance in preventing impairment to human health, or present a potential, unreasonable risk of illness or injury	Implantable pacemaker, HIV diagnostic tests, automated external defibrillators
Humanitarian Device Exemption (HDE)	Device that is intended to benefit patients by treating or diagnosing a disease or condition that is "orphan" (Affects fewer than 4,000 individuals in the US/year). HDEs are exempt from requirements to demonstrate effectiveness. Still, they must pose no unreasonable risks	Liposorber, Retinal Prosthesis systems

Adopted from FDA

Figure 4.5: Classification of medical devices in the U.S



Class of Device	Examples
Class I	Band Aids, Crutches, Wheel chair, surgical beds,
Class IIa	Dental fillers, Diagnostic Ultrasonic devices, Hearing aids, Contact lenses, Tooth crown, Syringes for single use
Class IIb	Anesthetic devices, Respiratory devices, X-rays, Blood bags, Defibrillator, Dialysis devices, Infusion Pumps
Class III	Heart Catheter, Coronary stents, Heart valves, Breast Implants, Pacemaker

Adopted from CE marking EC

Figure 4.6: Classification of medical devices in the EU

B.1 Medical Device Cassification in the EU

In the EU, classification of medical devices is the first step in the approval process and comes under the heading of "Conformity Assessment", where the manufacturers demonstrates the compliance of the product with the "Essential Requirements of safety and performance of MDs" [24]

In Europe, medical devices are assigned to one of the four regulatory classes[25]:

1. **Class I**: Low risk medical devices
2. **Class IIa**: Medium risk medical devices
3. **Class IIb**: High risk medical devices
4. **Class III**: Very high risk medical devices

The classification of a device is governed by classification rules, described in Annex IX of the MDD. These rules are based on criteria such as duration of use, invasive nature, contact with critical parts of the body, biological effect and the supply of energy. To facilitate the

use of the classification rules, a guidance document containing explanations and examples was written. If a new medical device is developed, it can be classified by applying the classification rules. This does not require a special decision by any regulatory body. In case of doubt, a Notified Body or a Competent Authority can be asked to preside[26] .

B.2 Medical Device Classification in the U.S

In the U.S following classification of medical devices is followed[27]:

1. **Class I:** Devices which is of substantial importance in supporting, sustaining or preventing impairment of human life or health, and do not present a potential unreasonable risk of illness or injury.
2. **Class II:** Devices for which it is necessary to establish a performance standard, in order to provide reasonable assurance of safety and effectiveness.
3. **Class III:** Devices for which insufficient information is available to establish a performance standard. These devices support and sustain human life or present a potential unreasonable risk of illness or injury.
4. **Humanitarian Device Exemption (HDE):** Device that is intended to benefit patients by treating or diagnosing a disease or condition that is termed as 'orphan' .

FDA has organized 18 medical specialty panels, in which approximately 1700 distinct types of devices are described. For each of these types of devices, a general description enlisting intended use, the class to which the device belongs to and information about marketing requirements are specified. A manufacturer can search the classification database or go to the applicable device panel and find the type of device there product comes under[27].

For a completely new and innovative device, the risk class cannot be established from this list and the FDA will have to be contacted to establish the risk class.

C. Procedures for Market Authorization

Market authorization procedures somewhat differ in both the U.S and the EU. In the U.S, the market authorization procedure for high risk devices does not allow equivalence with other similar products to be used for easier market authorization and the manufacturer is always required to perform one or more clinical studies, which might take one or more years. While in Europe for the high risk devices, equivalence can be used as part of the market authorization procedure. This contrast explains why certain devices can take several

years longer to come onto the USA market, compared to Europe. Also, in the U.S for high risk devices, it is specified that non-clinical laboratory studies and clinical studies involving human subjects need to be included while in Europe, generally, "essential requirements" related to safety, performance, design and construction are listed, to which the manufacturer has to demonstrate compliance, as far as applicable, for their specific medical devices [21]

C.1 Market authorization procedures in the U.S

Once the classification for the new product is determined, the correct market submission procedure has to be followed. There are two main procedures for market submission requiring FDA involvement[28]

a. Pre-market Notification or 510 (k)

b. Pre-market Approval (PMA)

In general, these rules apply to the various classes:

i. Most Class I devices are exempt from 510 (k)
ii. Most Class II devices require 510 (k)
iii. Most Class III devices require PMA

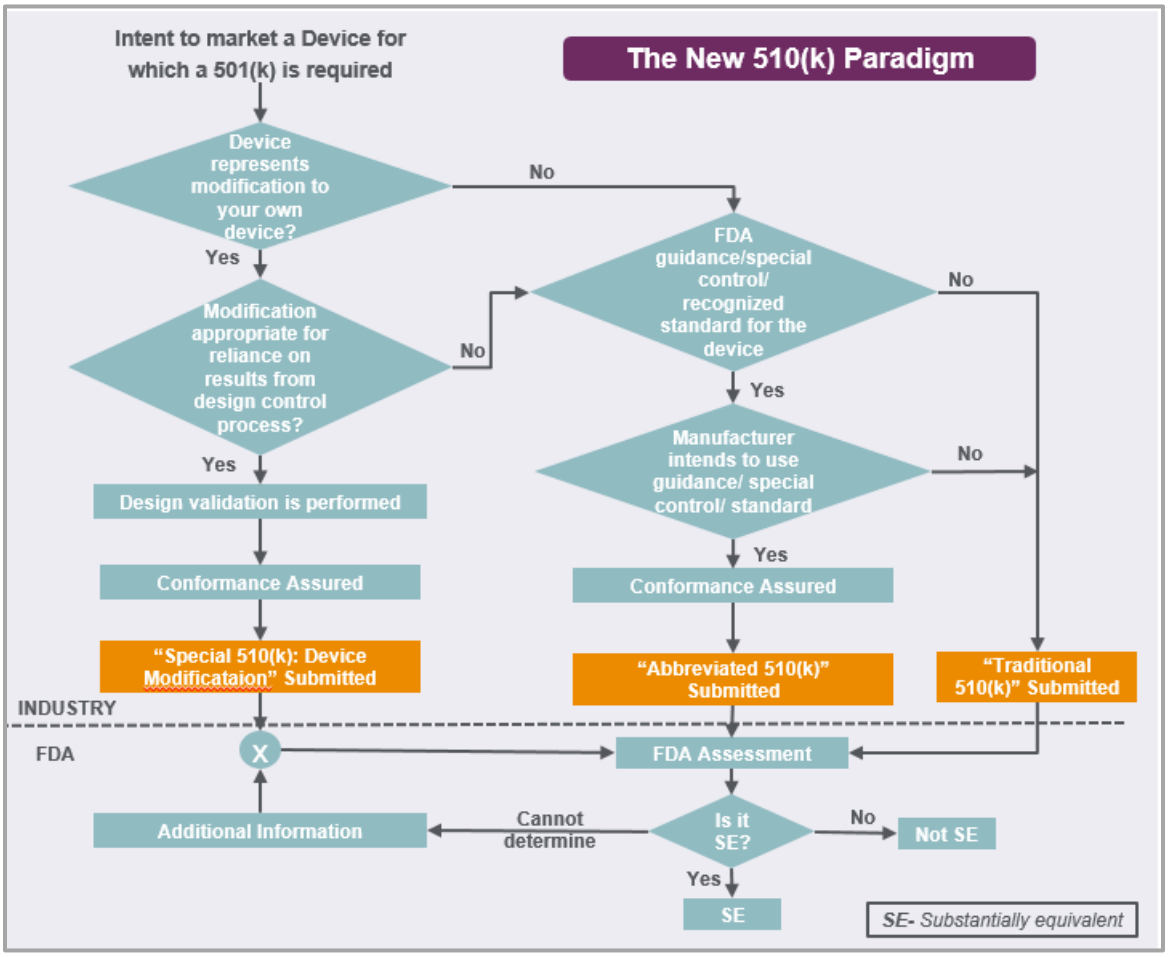
The most stringent form of market submission in U.S is the PMA procedure, for which the manufacturer has to submit an extensive set of documents to the FDA, while for the 510 (k) procedure, the manufacturer has to show that his device is substantially equivalent to another, already marketed device. The route of substantial equivalence is only valid for eligible devices (mostly Class II) and not for any device for which a substantial equivalent device is available [29, 30]

C.1.1 Pre-market Notification 510 (k)

A 510 (k) is a pre-market notification to the FDA in which it is shown that the device to be marketed is at least as safe and effective as a similar device which is already legally marketed in the USA. This approach is valid for most Class II devices. This comparison with an existing similar device is called showing substantial equivalence, and the existing device that is used for comparison is called the predicate[21]

The mandatory elements of a 510 (k) include (amongst others) [30]:

1. A sufficiently detailed description of the device, allowing the determination of substantial equivalence.
2. An identification of the predicate device, to which substantial equivalence is claimed.
3. An explanation of the intended use of the device. When these explanations differ from the predicate, an additional explanation must be provided, describing why these differences will not have an influence on the safety and effectiveness of the device.
4. If the device has the same technological characteristics as the predicate, a summary must be provided in which the technological characteristics of the new device are compared to the predicate. If the device has different technological characteristics, a summary must be provided in which it is explained in what way the technological characteristics are similar to the predicate's characteristics.



Adopted from: FDA

Figure 4.7: FDA Pre-market Notification 510(k)

For Class II devices, regulatory requirements are attributed as special controls. Special controls are usually device specific and incorporates [21,30]:

i. Performance standards
ii. Post-market surveillance (PMS)
iii. Patient registries
iv. Special labeling requirements
v. Pre-market data requirements
vi. Guidelines

Exemption: Class I medical devices exempted from 510 (k) notification while in some cases, Class III devices can obtain market authorization using the 510 (k) procedure. For example: a metal-on-metal hip implant.

C.1.2 Pre-market Approval (PMA) [29]

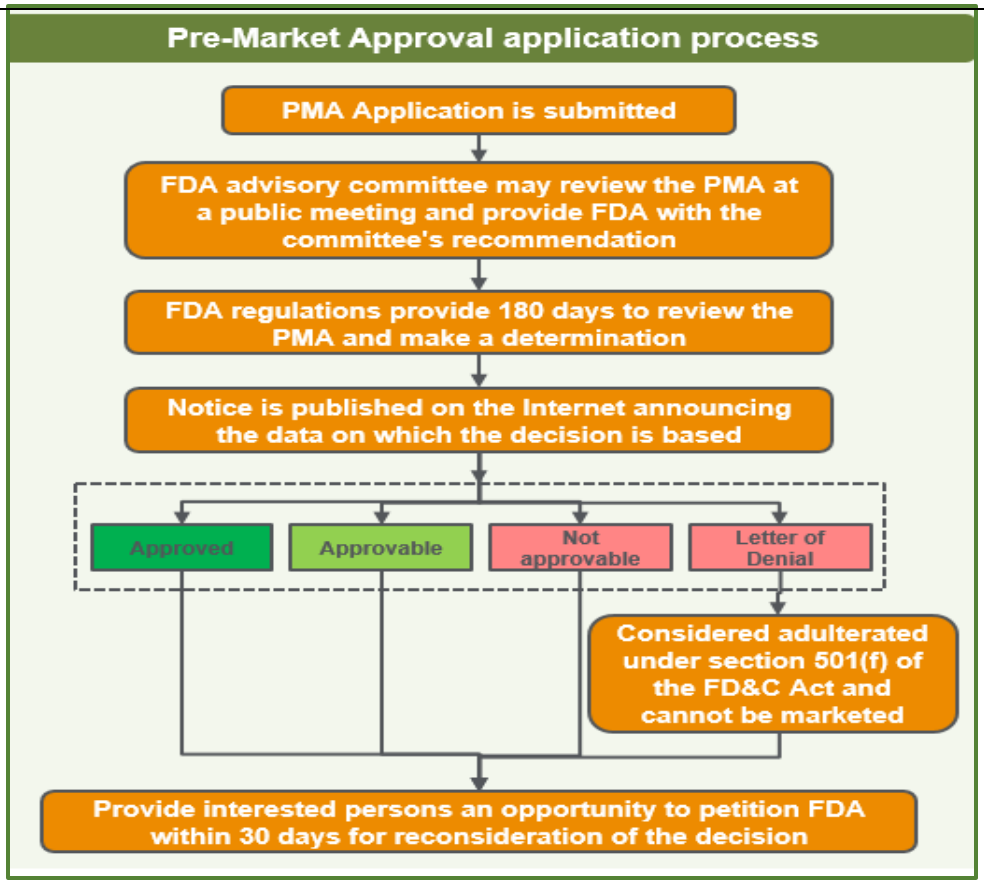
PMA is the assessment process of the FDA for the safety and effectiveness of most Class III medical devices. Because of the high risks associated with these devices, FDA has determined that special controls alone are not satisfactory to guarantee safety and effectiveness of the product. Therefore, a PMA is required for these devices.

The PMA documentation submitted by the manufacturer, includes both administrative elements and scientific evidence sections.

There are two scientific evidence sections in a PMA application:

i. **Non-clinical research**: This section contains information on, the microbiology, toxicology, immunology, bio compatibility, wear and shelf life of the product. Non-clinical research has to be performed in accordance with certain regulations, defined in 21 CFR Part 58.
ii. **Clinical research:** This section has to contain study protocols, safety and effectiveness data, adverse reactions and complications, patient information and results.

A Class III medical device with a denied PMA is considered to be adulterated, and is not allowed to be marketed. This procedure for market authorization is used for about one percent of all devices allowed onto the USA market. [31]

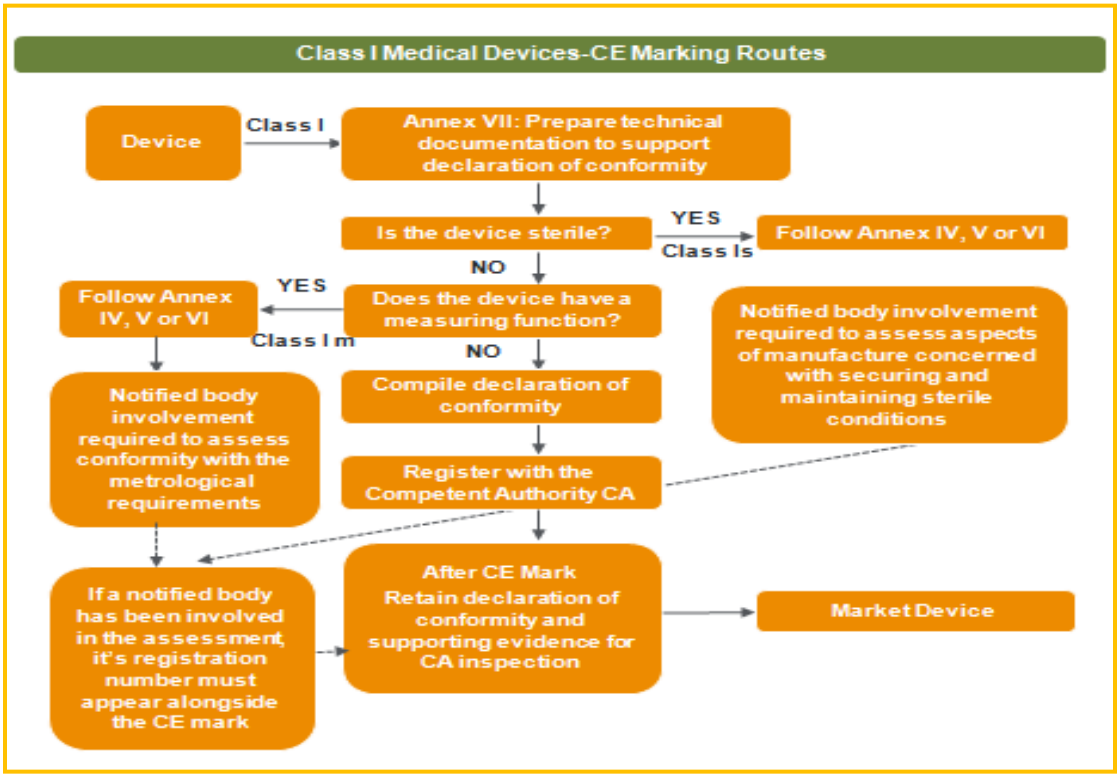


Adopted from: FDA

Figure 4.8: FDA Pre-market Approval for Medical Devices in U.S

C.2 Market authorization procedures in the EU

C.2.1 Class I market authorization process

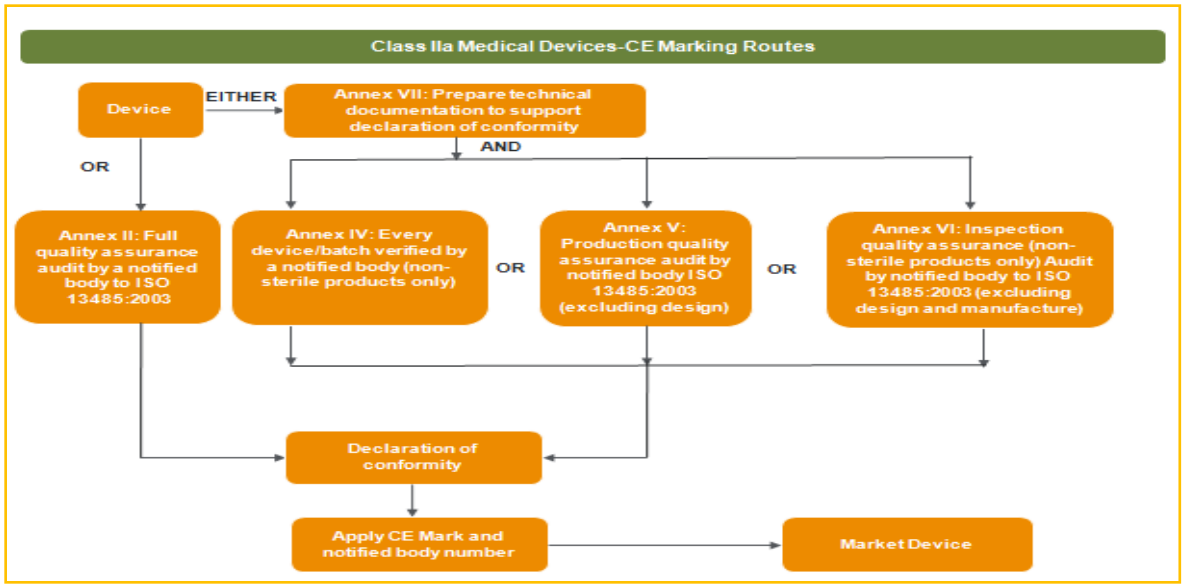


Adopted from: CE marking

Figure 4.9: CE marking route for Class I Medical Devices

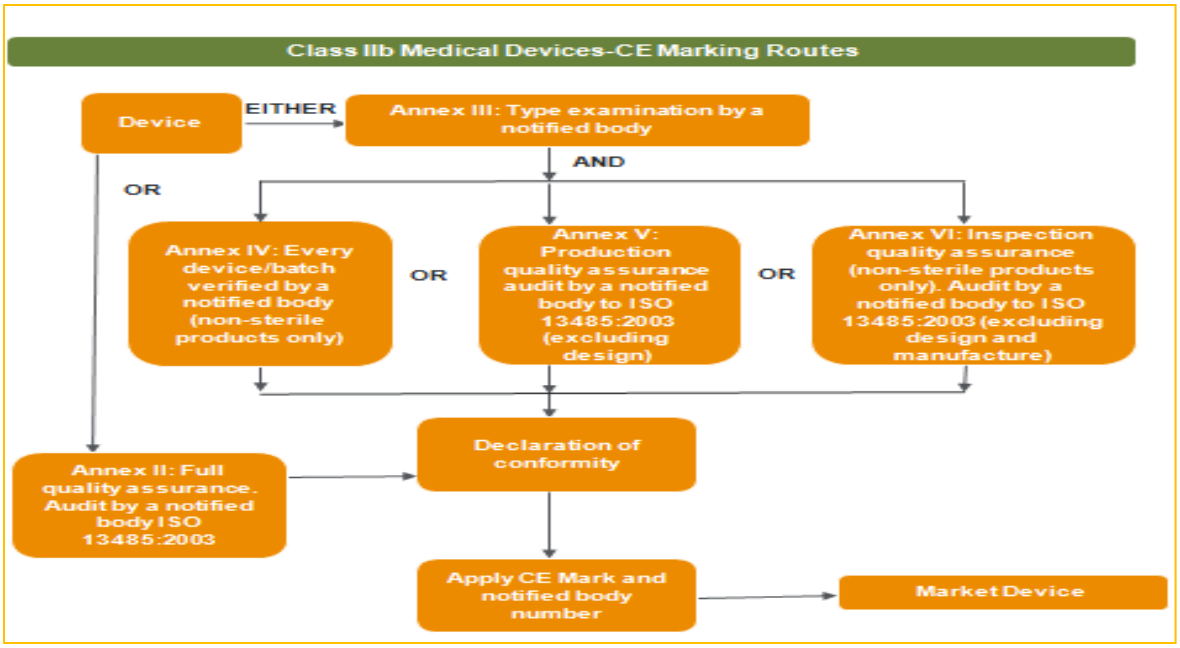
For Class I medical devices, the conformity assessment procedure is performed with the intervention of an external party. However, two specific groups of Class I devices are defined for which there is limited intervention of external parties for the assessment procedure: sterile devices (Class Is) and devices with a measuring function (Im). Notified bodies are involved in the conformity assessment procedures (CAP) for Class I devices.[32]

C.2.2 Class II market authorization process



Adopted from: CE marking

Figure 4.10: CE marking route for Class IIa Medical Devices

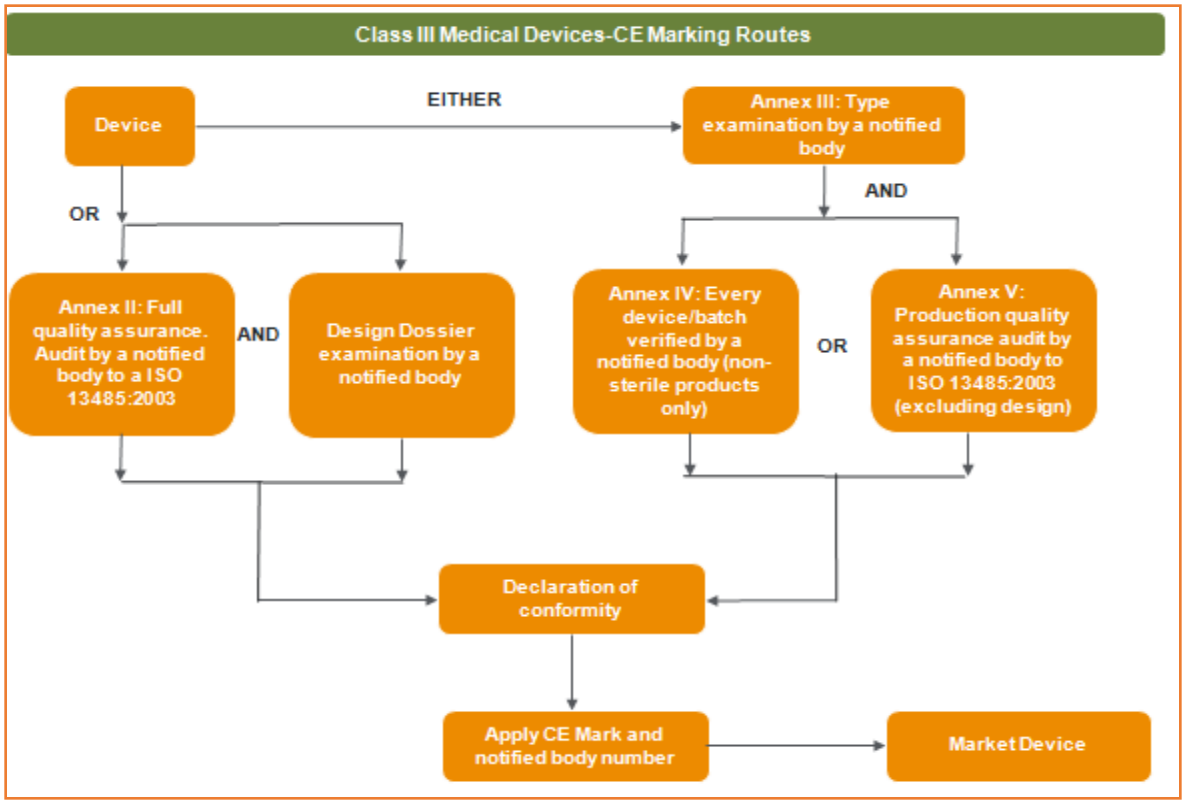


Adopted from: CE marking

Figure 4.11: CE marking route for Class IIb Medical Devices

The stringency of the involvement of the Notified bodies increases when the device class rises from I to IIa and IIb. For Class II, the full quality assurance system is implied in the design, manufacture and final inspection of the device and is subjected to audit and surveillance by Notified bodies[33,34]

C.2.3 Class III market authorization process



Adopted from: CE marking

Figure 2: CE marking route for Class III Medical Devices

For Class III, the regulations and the satisfactory criteria required to be fulfilled further becomes complicated and extensive. Many annexures and their implications have to be covered, including EC verification, production quality assurance, EC declaration of conformity under the authority of the Notified Bodies [35]

D. Registration of manufacturers and medical devices

D.1 Registration of manufacturers and medical devices in the U.S

For owners or operators in the medical device business, it is required to register annually with the FDA, if they are involved in the production and distribution of medical devices intended for use in the US. Most establishments that are required to register with the FDA

are also required "to list the devices that are made there and the activities that are performed on those devices". [36]

Registration and listing provides FDA with the location of medical device establishments/facilities and the devices manufactured at those establishments. Knowing where devices are produced increases the ability to prepare for and respond to public health emergencies. [37]

D.2 Registration of manufacturers and medical devices in the EU

In Europe, according to Article 14 of the MDD, manufacturers (or their authorized representatives) of devices belonging to Class I, leaving aside devices which are custom-made or intended for clinical investigations, are required to register with a Competent Authority namely the Notified bodies before placing their respective medical devices on the EU market. [21]

The Competent Authority must be in an EU member state where the registered manufacturer is located. If a manufacturer has no registered place of business in an EU member state, a legal person (distribution partner/wholesaler) established in the EU must be designated to act on his behalf, called as authorized representative [38]

E. Marking of the medical devices

Any "medical device that is legally placed on the European market should bear a CE mark. If a Notified Body is involved in the market authorization procedure, the identification number of that Notified Body should accompany the CE (Conformité Européenne) mark. However, there doesn't seem to be an FDA approval/official mark for medical devices"[39]

F. Time frame for approval

USA

Time frames are given to the FDA when processing: 180 days for PMA approvals and 90 days 510 (k) approvals. However, FDA does not always meet the required time frames [40].

E.U

In the medical device legislation no specific time frame is mentioned. However, in practice clients can negotiate with the Notified Body involved in how long it will take to

obtain a decision on authorization. An estimated time frame of 210 days is laid down for medical devices.

G. Post-marketing requirements

G.1 Vigilance and post-market surveillance

USA

Manufacturers have to report to the FDA, incidents and adverse events requiring remedial action to prevent an unreasonable risk of substantial harm to the public health. The FDA can request additional information of the manufacturer if it is deemed necessary to safeguard public health. Manufacturers are required to report to FDA when one of their marketed devices has or may have caused/contributed to a death, serious injury, or has malfunctioned. It is the responsibility of the manufacturer to evaluate whether an event is reportable or not.[41]

Device user facilities, namely hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities are required to report [42]:

i. Device related deaths to the FDA and the device manufacturer.
ii. Device related serious injuries to the manufacturer, or to the FDA if the manufacturer is not known.
iii. Submit to FDA on an annual basis a summary of all reports submitted during that period.

Europe

The MDD requires manufacturers, irrespective of the device class, to institute and keep up to date a systematic procedure to review the experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. Examples of information sources are complaints, literature, customer surveys. The clinical evaluation has to be constantly updated with data obtained from post-market surveillance. [43]

The obligation to notify the authorities in case of incidents and taking appropriate action is known as a vigilance system. There are certain corrective action that can be required following an incident:

i. A device recall.
ii. The issue of a field safety notice.
iii. Additional surveillance/modification of devices in use.
iv. Modification to future device design, components or manufacturing process.
v. Modification to labelling or instructions for use.

G.2 Distribution and sales channels

USA

Manufacturers (both domestic and foreign) and initial distributors of medical devices must register their establishments with the FDA. This provides FDA insight into the distribution channels. [21]

Europe

There are no requirements for the distribution or sale of medical devices in the MDD.Only manufacturers of Class I and custom made devices are required to register themselves with the national Competent Authorities [21]

G.3 Supervision and Recall

USA

The FDA can perform inspections at the manufacturer's site, albeit no guidelines on the reasons and frequency of these inspections could be found. A recall is often voluntarily initiated by the manufacturer, however a recall can also be initiated by the FDA to protect public health or as a consequence of serious deceit. A recall always has to be notified to the FDA .[21]

Europe

After CE certification the EU member states are responsible for ensuring that the medical devices, when correctly installed, maintained and used for their intended purpose, do not compromise the health or safety of patients, users or other persons. Incidents must be notified to the relevant national Competent Authorities (Notified Bodies) by the manufacturer or the Authorized Representative. A recall is often initiated by the manufacturer itself. [21]

4.3 To assess and differentiate medical device financing by the government and the reimbursement process for medical devices in the USA and Europe

4.3.1 Patient access and reimbursement process for medical devices

Patient access is equated with the availability of the reimbursement money to the manufacturers which is paid by a national or a third party payer, which in turn ensures that the medical device is made available to the patient. Public or private insurers decide whether and at what price they will pay for a device referred to as reimbursement tariffs. Generally, public system (government) takes longer time frame to make reimbursement decisions as compared to their private counterpart. . Reimbursement procedure in any region greatly depends on the type of insurance coverage availed by its inhabitants, whether they are covered under national health insurance schemes or if they buy private health insurances to protect themselves from the OOP. Insurers must approve a new product or service, and its pricing, before they will pay for the device in question and make it available to the patients.[44]

When assessed, comparatively more Europeans are covered under public health insurance as compared to Americans. Two thirds of the U.S. population are covered by private health insurance, whereas only a fifth receives publicly funded reimbursement, primarily administered by the Centers for Medicare and Medicaid Services (CMS).

In US upon FDA approval CMS (Centers for Medicare and Medicaid Services) provides reimbursement for the majority of medical devices, with the exception for few devices which are still not included in the country's list of reimbursable medical devices. On the contrary, in Europe especially in EU-5 countries, medical devices on being granted CE-mark are evaluated by the respective regulatory authorities present in different countries before being reimbursed especially in the public sector. European countries usually require additional data on the device's safety and effectiveness, as well as on cost-effectiveness, referred to as *techno-economic evaluation* before including it on the National List of reimbursable medical devices.

To gain patient access also greatly depends on the innovativeness of the medical device in question because such devices require the strongest evidence of clinical benefit, risk involved, cost effectiveness and are the subject of most debates about the relative effectiveness of approval processes in different countries[45, 46]

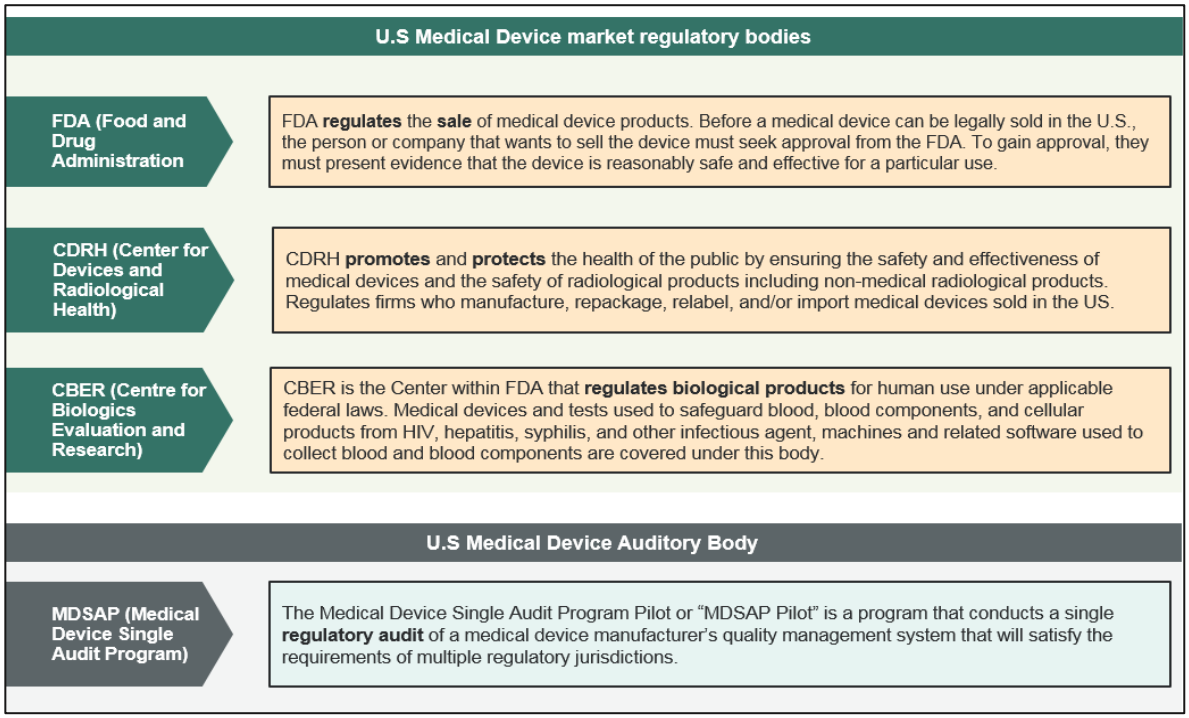
A. Regulatory/ Decision making bodies involved in the Reimbursement process

A medical device journey in the reimbursement process starts from getting enlisted in the system and ends with receiving payment (reimbursement) before being made available in the market. This process is distinctive for each country and requires involvement of many regulatory and decision making bodies. It's a highly distinct process which varies for different medical devices depending on their specialization or the medical procedures in which they are utilized.

A.1 *USA*

The reimbursement system in the U.S is based on a mixed public/private and third party payment system whereby government and individuals share the cost of care. Premiums are paid to private insurance companies for private coverage by individuals. Regulation of the reimbursement process and the medical devices is done by the regulatory bodies active at the national level.

U.S medical device regulatory bodies include: FDA (Food and Drug Administration), CDRH (Center for Devices and Radiological Health), CBER (Center for Biologics Evaluation and Research) and MDSAP (Medical Device Single Audit Program)[47].



Adopted from FDA

Figure 4.13: Regulatory Bodies in the US for medical device industry

Decision makers involved in granting reimbursement for medical devices in U.S[48]:

i. **Medicare:** Medicare is a federal health insurance program. Medicare is the largest single payer in the United States and plays a significant role in setting reimbursement. Medicare can create national or local coverage policies under National and Local Coverage determination.

ii. **Medicaid:** Medicaid is a U.S. health insurance program that provides care to qualifying people who cannot pay for their own medical expenses. Medicaid is conjointly funded by both the federal government and each of the individual states.

iii. **Private Payers:** Private payers cover all Americans who self-pay for their services. Private payers have payer specific coverage, payment tariffs and technology assessment processes. There are both national and regions based private payers.

A.2 *Europe*

In Europe, especially the EU-5 countries, each country have its own set of national and local bodies, who have the job of enlisting the medical devices on the national formulary list before allocating reimbursement under their respective national trusts/ health insurance schemes.

Germany[49]

Table 4.2: Regulatory bodies for Medical Devices in Germany

Adopted from Distasis

On country level:		On state level:	
Body	Duty	Body	Duty
Ministry of Health (BMG)	Legislation and functional supervision	Supreme State Authority (Oberste Landesbehörde)	Participation in legislation and functional supervision
State institute for pharmaceuticals and medical devices (BfArM)	Approval of clinical studies, vigilance system	State Surveillance Authorities	Market surveillance, Surveillance of users
German Institute for medical documentation and information (DIMDI)	Data bases	Central Bureau of the states for health safety with drugs and medical products (ZLG)	Designation and surveillance of Notified Bodies
Physical-technical federal institute (PTB)	Metrology	**Notified Bodies:** • Neutral auditing/certifying/examining bureaus for product and quality management (e.g. TÜV, DEKRA)	
Robert-Koch-Institute	Hygiene		

Decision makers and influencers

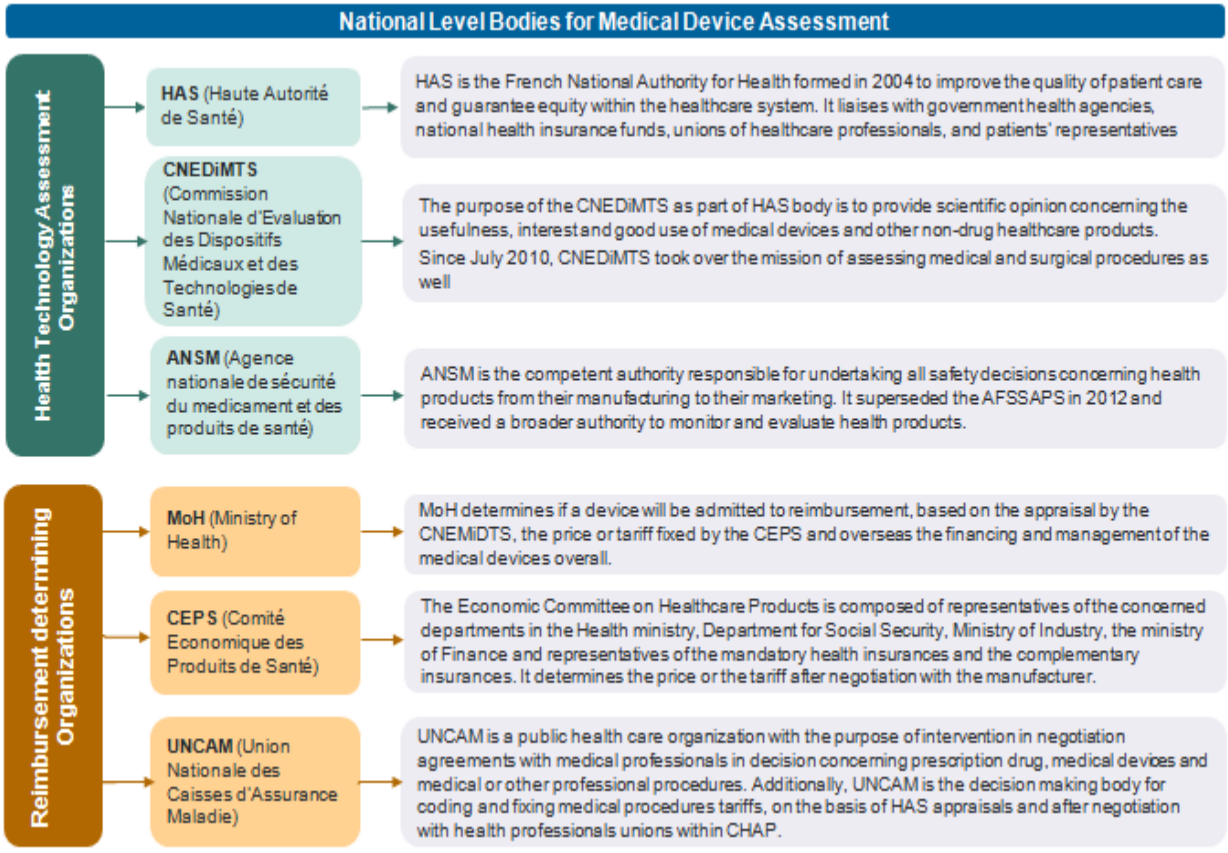
- **DIMDI** - (German Institute of Medical Documentation and Information): Maintains diagnostic (ICD-10-GM) and procedural (OPS) coding.
- **InEK** - (Institute for the Hospital Remuneration System): Maintenance of G-DRG codes and associated reimbursement rates. Handling of applications for NUB (see below) and monitoring of NUB utilization.
- **G-BA** - (Joint Federal Committee): Ratification of new procedures for coverage by the SHI.
- **Review Committee** (Representatives from SHI and SHI doctors association): Maintains the EBM catalogue (see below), which is the basis for the fee for service remuneration of providers.
- **IQWiG** - (Institute for Quality and Efficiency in Healthcare): May conduct health technology assessments if requested by G-BA.
- **SHI** - (Statutory Health Insurance): pays for services provided based on G-DRG or EBM

Adopted from Distasis

Figure 4.14: Decision making bodies for medical devices in Germany

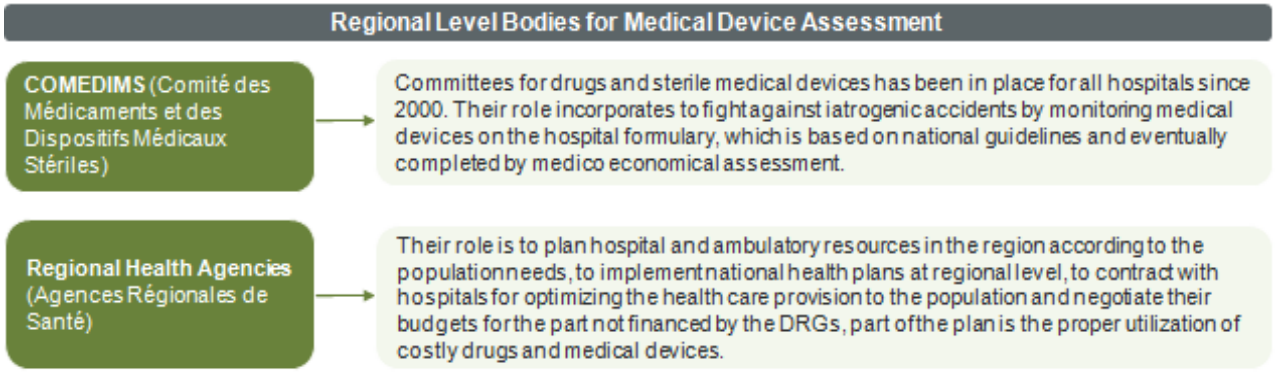
France[50]

Regulatory and decision making bodies for medical devices are segregated at the national and regional level. Further, they are segregated into Health Technology Assessment and Reimbursement determining organizations.



Adopted from ispor

Figure 4.3: Regulatory and decision-making bodies in France for Medical Devices at national level

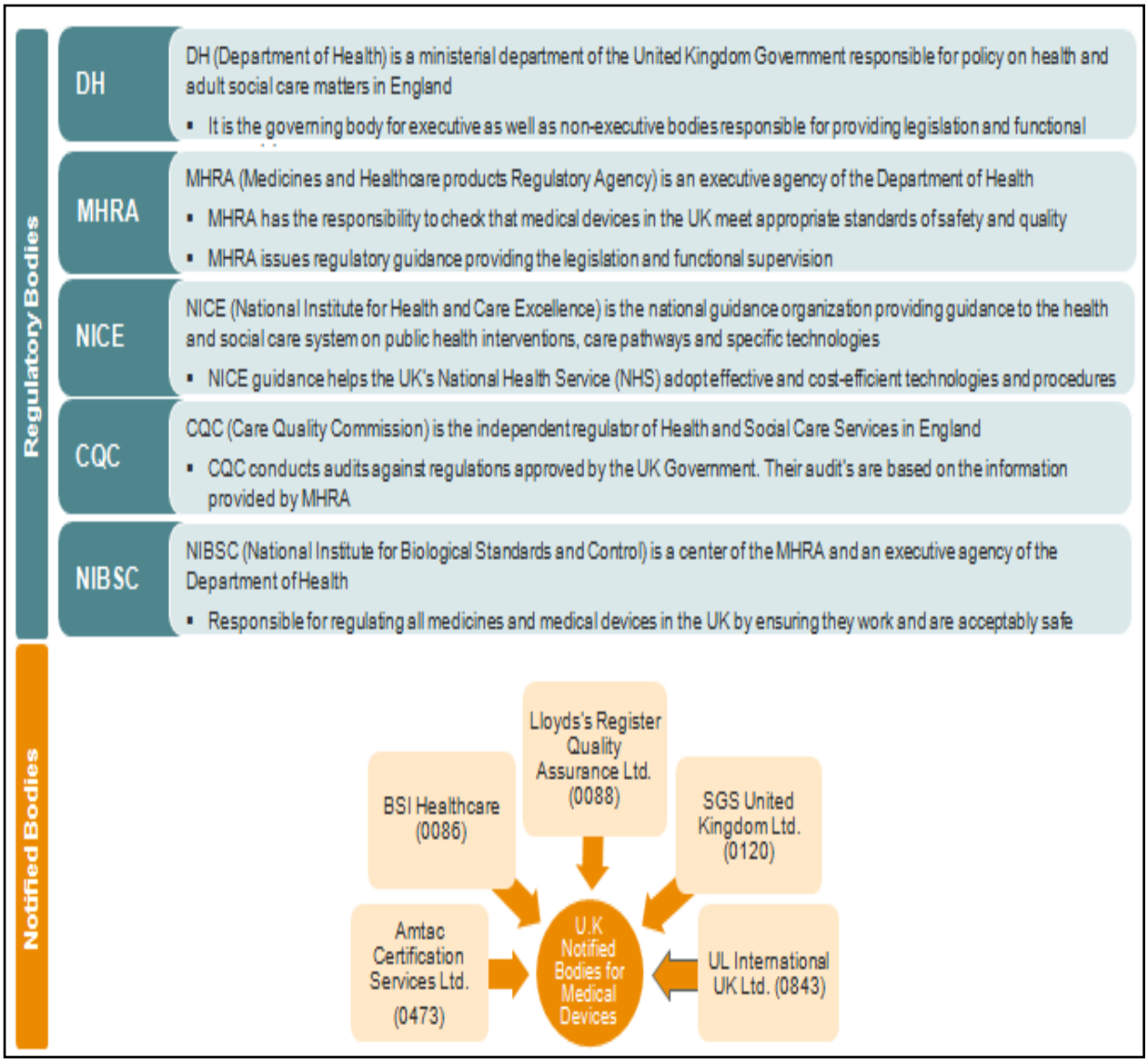


Adopted from ispor

Figure 4.4: Regulatory/ Decision making bodies at the regional level

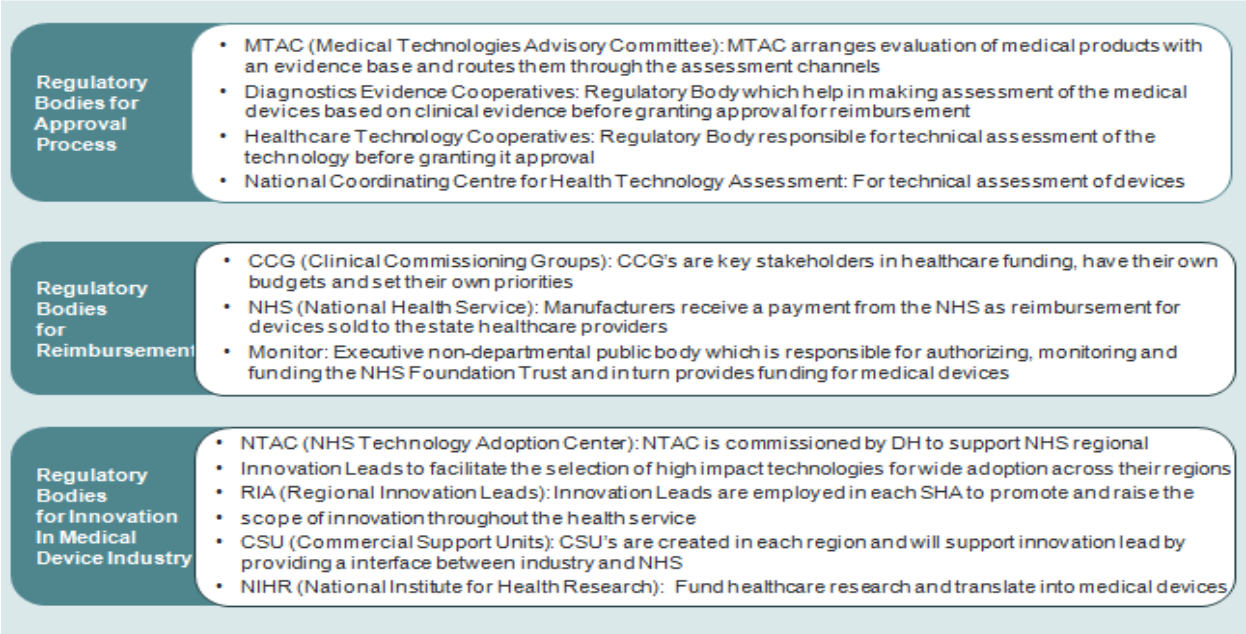
In France, UNCAM (*Union Nationale des Caisses d'Assurance Maladie*), is the new public health care organizational system. Its first purpose is to coordinate the three mandatory sickness funds, form links with complementary scheme and with health care professionals, to obtain a better health insurance management. Its second purpose is the intervention in the negotiation of agreements with medical professionals in the decision concerning a prescription drug, medical devices and medical or other professional procedures. In addition, UNCAM is the decision making body for coding and fixing medical procedure tariffs, on the basis of appraisals and after negotiation with health professional unions within a specific committee.

United Kingdom[51]



Adopted from: ispor

Figure 4.5: Regulatory Bodies governing Medical Devices in the U.K

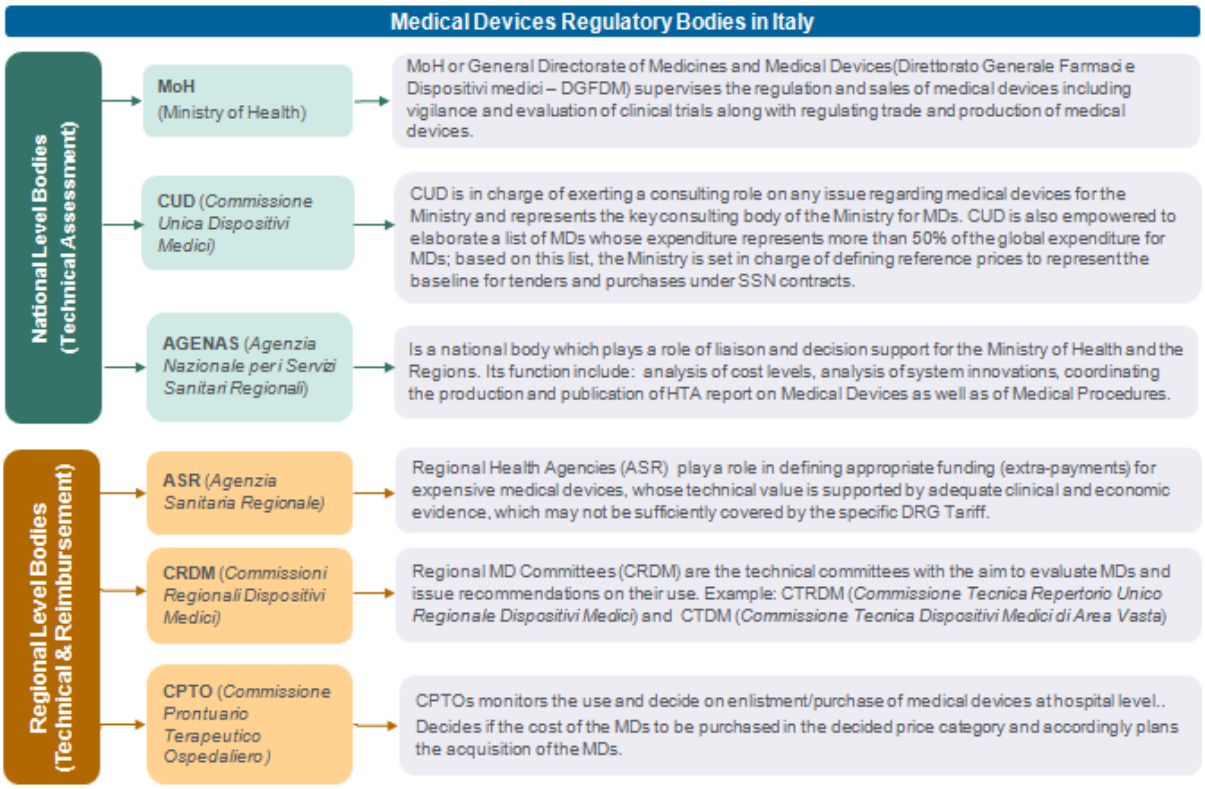


Adopted from: ispor

Figure 4.6: Regulatory Bodies acting on specific areas of reimbursement of Medical Products in the U.K

Same as other European countries, there are regulatory and notified bodies acting on various steps of the reimbursement process, namely the technology assessment, funding for reimbursement procedure and bodies for innovative medical devices.

Italy[52]

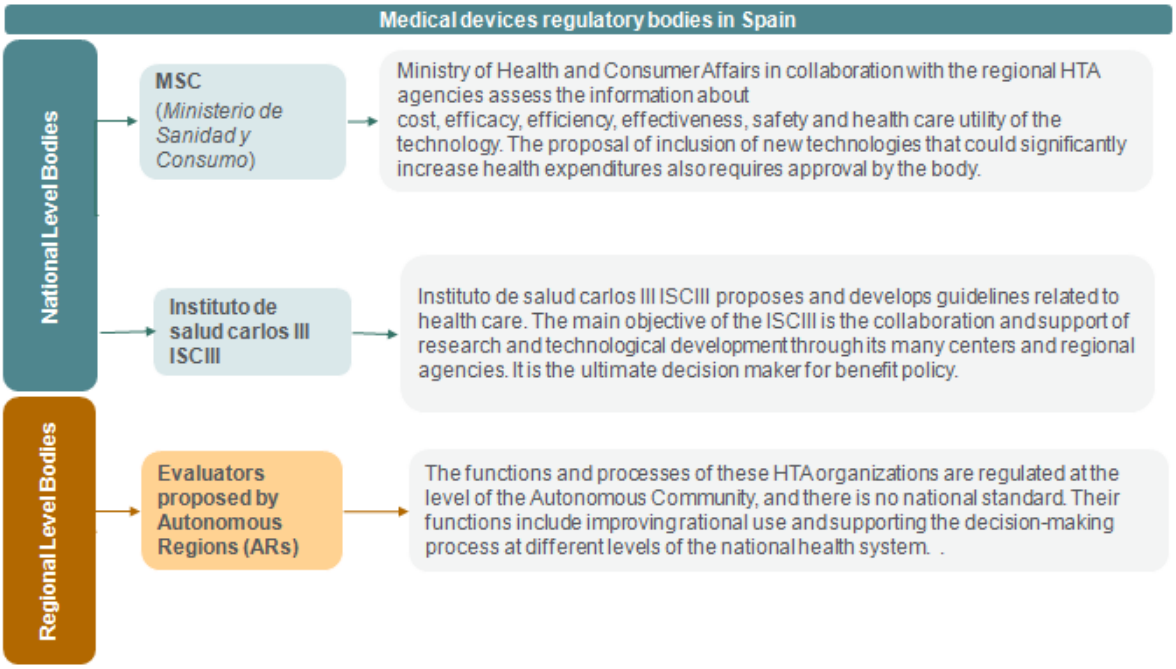


Adopted from: ispor

Figure 4.7: Regulatory/ Decision making bodies at national and regional level in Italy

Medical Devices in Italy are not subjected to P&R negotiation at the central level, thus funding must be queried at the local level. Italy has a decentralized system where procurement and reimbursement of medical devices takes place at the regional level with the level of tariffs varying with different regions.

Spain[53]



Adopted from: ispor

Figure 4.8: Regulatory/ Decision making bodies in Spain

In Spain, pricing and reimbursement occur at the regional level where regions are referred to as Autonomous Regions. The major decision making falls on the regional level bodies who in coordination with the national bodies come to a consensus to either select or reject the medical device to be covered under the health coverage.

B. Reimbursement process for medical devices

***Reimbursement*:** Is a blanket term "describing how commercial insurance plans or the government pays for the items or services provided by medical professionals."

Key components of reimbursement

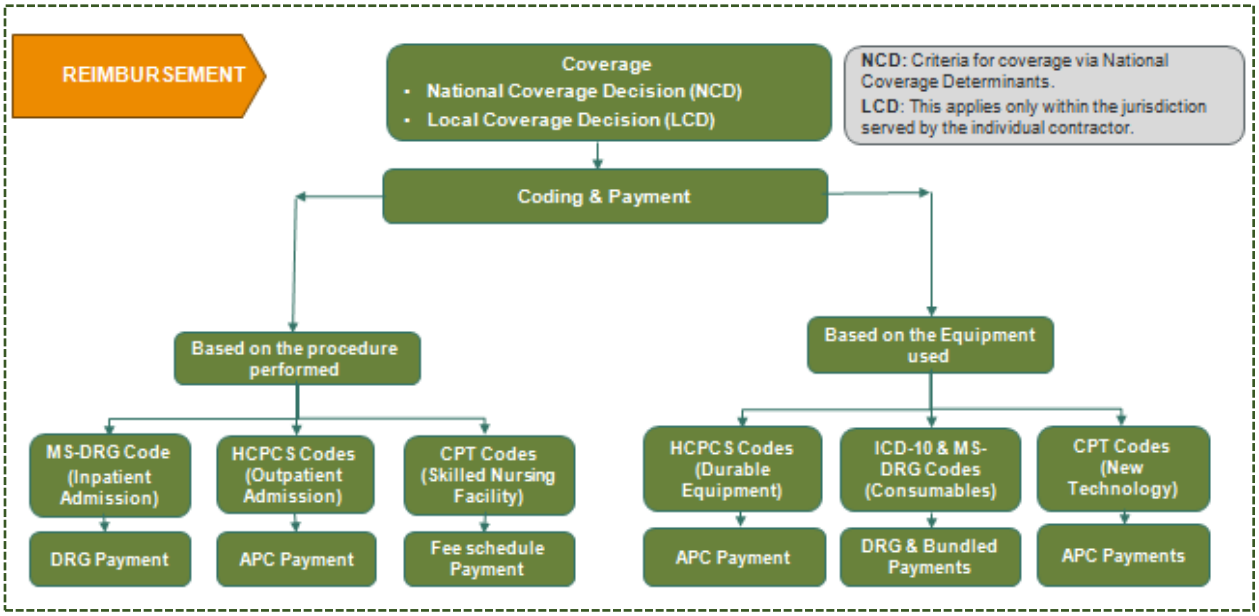
Coverage (payment criteria for a product, service or procedure), coding (mechanism for identification of a product, service or procedure), and payment (amount paid) are essential elements to obtaining adequate reimbursement for a new/ innovative or existing medical

devices. It is challenging for a medical device company to fulfill the criteria for novelty, the superiority of the product and criteria for safety and efficacy. [54]

Importance of reimbursement

Reimbursement is an integral part of developing and marketing a medical device. Reimbursement strategy is imperative for acceptance and success of a medical device in the market. It is crucial for a medical device company to obtain coverage and attract risk-averse investors. In the case of uncertainty of reimbursement for a particular device, securing funding becomes difficult. Also, whether a device is reimbursable or not and the cost of reimbursement are key factors that determine product demand and commercial success [54]

B.1 *USA*



Adapted from FDA

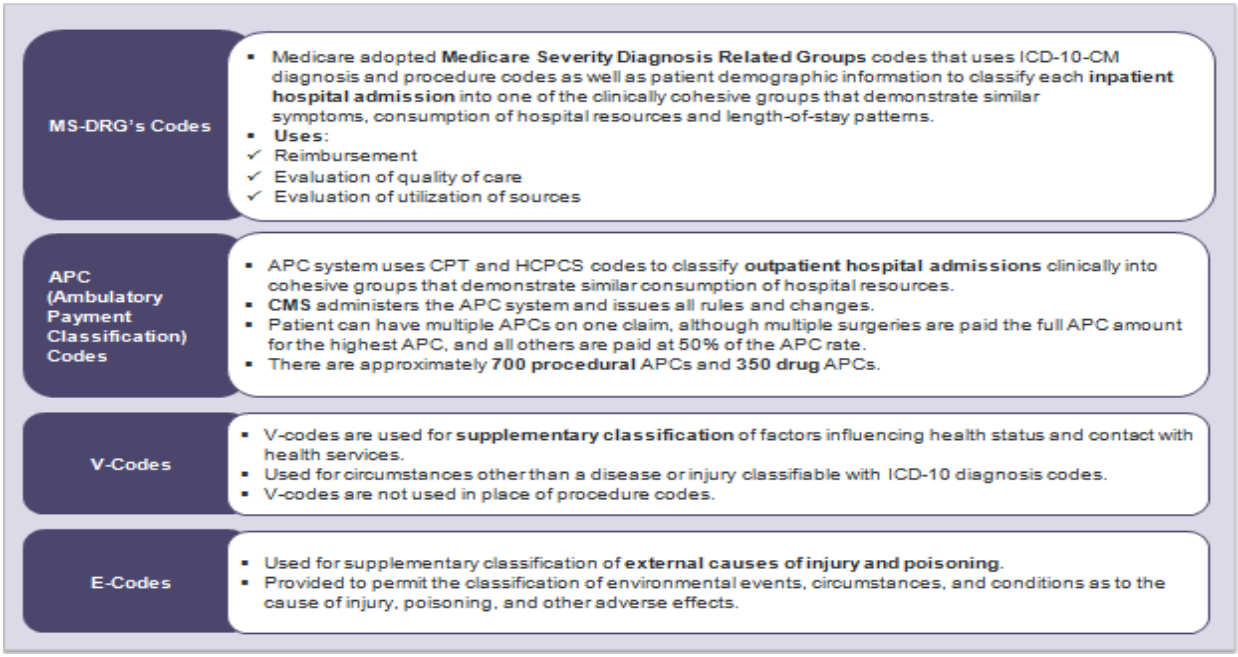
Figure 4.9: Reimbursement model for U.S Medical Devices

Coverage in U.S [47]

Referred to as decisions taken by third-party payers to include a service in the package of benefits available to beneficiaries. Coverage decisions influence payment determinations and affects patient access to new technologies. It typically includes an assessment of whether or not the technologies are "reasonable and necessary" or meet the respective payer medical necessity criteria. Coverage can be limited to certain sub-populations of patients based on disease severity or failure of previous therapies.

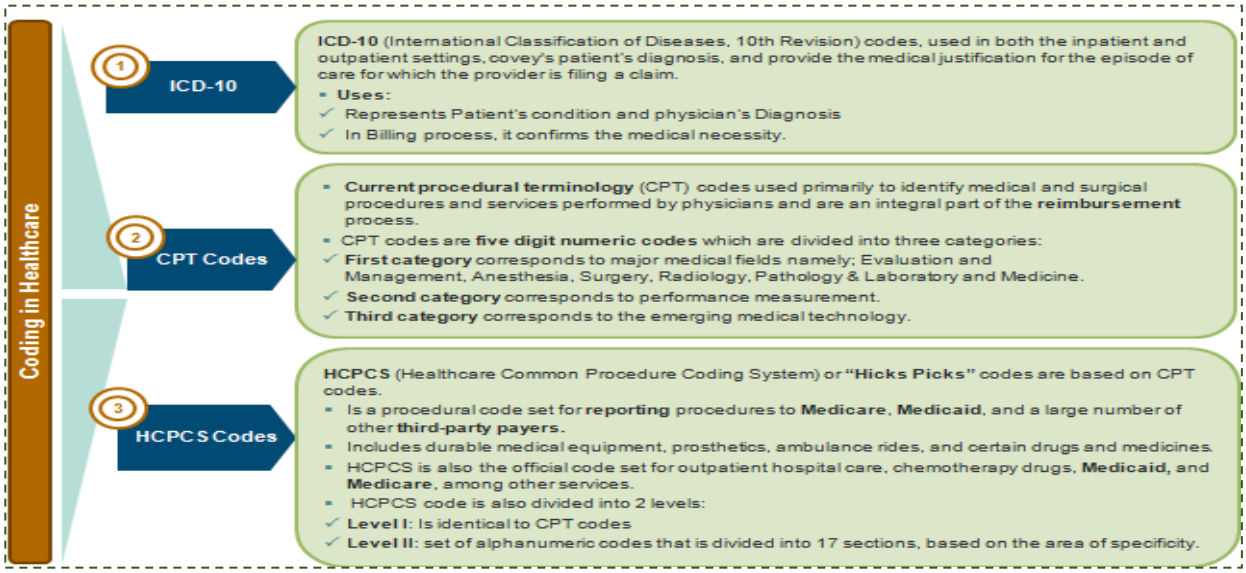
Coding in U.S [55]

The mechanism by which providers can bill payers for services rendered and/or costs incurred. Standardized system describing diseases, diagnoses, clinical procedures or medical products used for reporting, payment and statistical analysis. In US, coding is the language of CMS, private payers, facilities and physicians translating into payment.



Adopted from: FDA

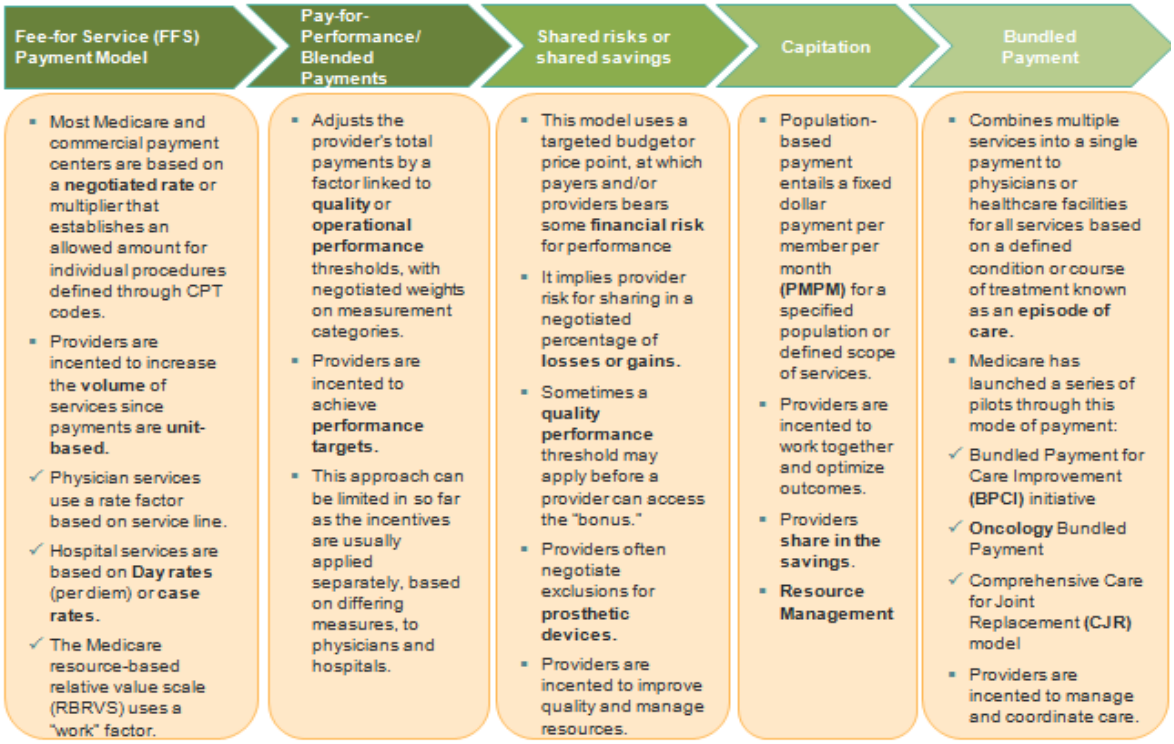
Figure 4.10: Codes under which medical devices are reimbursed in the USA



Adopted from: FDA

Figure 4.11: Codes in U.S Healthcare

Payment in U.S



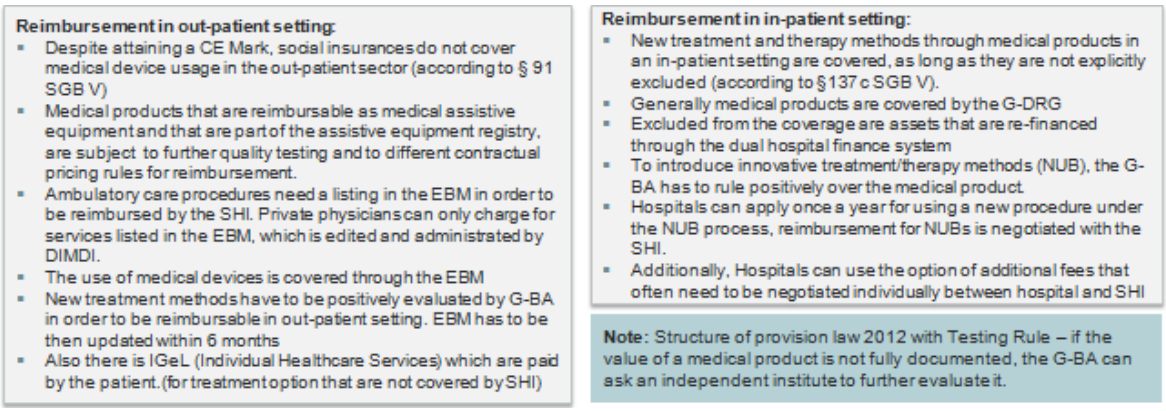
Adopted from: FDA

Figure 4.12: Different payment models for medical devices in U.S Healthcare

B.2 *Europe*

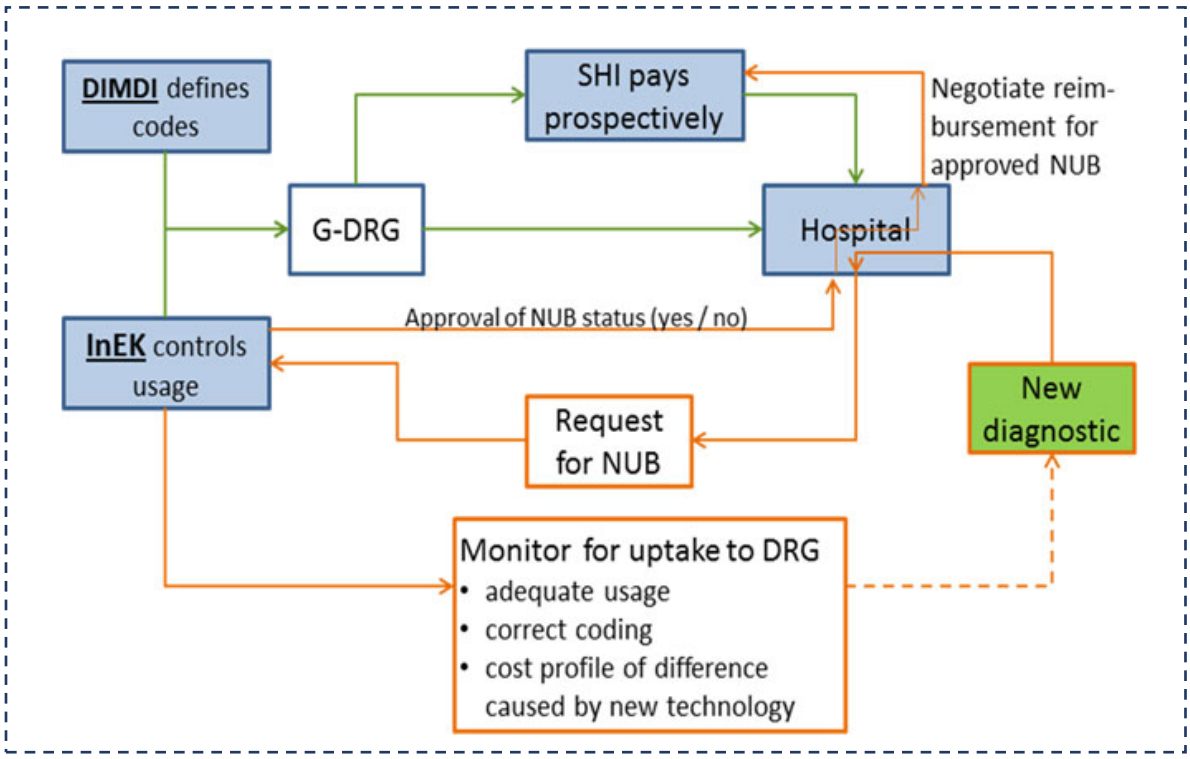
In Europe, different countries have distinctive reimbursement processes depending on many variable factors for the medical devices where, the payment is based upon the procedures in which they are used (inpatient or outpatient setting) or the category to which the device belongs to.

Germany[56]



Adopted from: Destasis

Figure 4.13: Reimbursement process for medical devices in Germany



Adopted from: ispor

Figure 4.14: Overall view of Medical Devices reimbursement in Germany

G-DRG System[49]

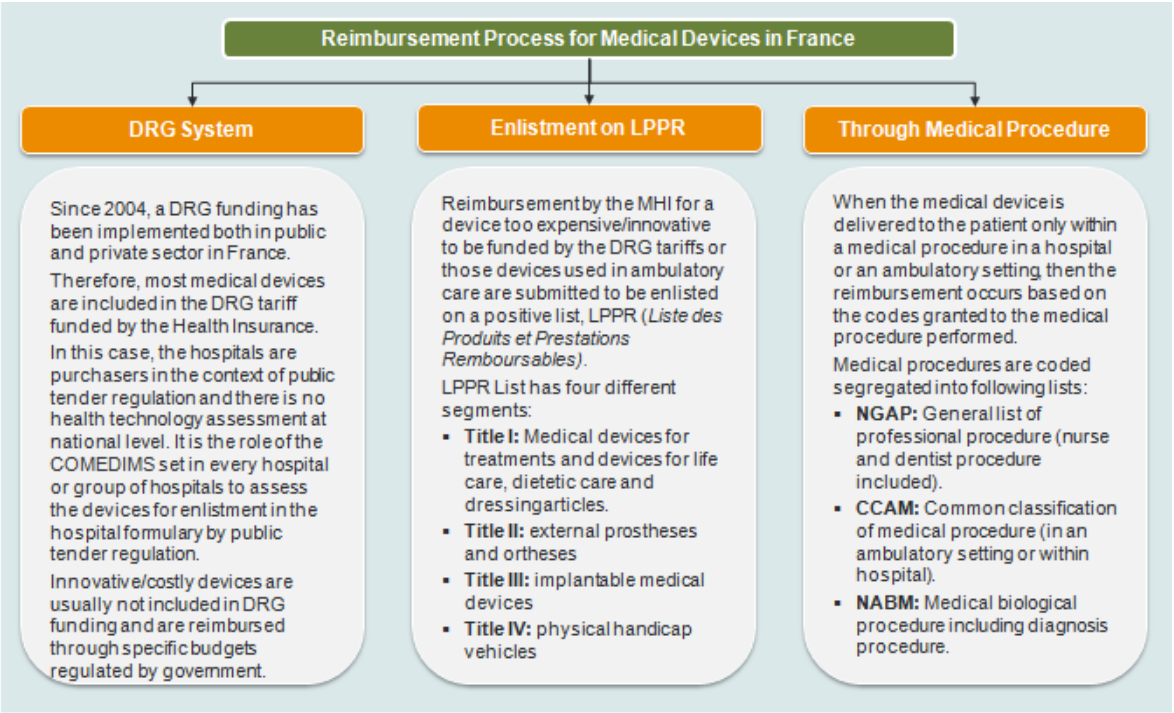
Different to other healthcare systems around the world, the G-DRG does not aim to incentivise, or disincentivise hospital activity; instead it aspires to accurately reimburse all activity types in a budget-neutral way for the hospital.

i. **German Diagnostic Code System:** The diagnostic code system employed by G-DRG is the ICD-10-GM "German Modification". DIMDI maintains and updates the ICD-10-GM on an annual basis. As the name implies, the system is based upon and closely resembles the ICD-10 maintained by the WHO.

ii. **German Procedure Code System:** Procedure codes in the G-DRG come from the OPS (Operationen- und ProzedurenSchlüssel) system which is also maintained by the DIMDI and also updated on an annual basis. In contrast with ICD-10-GM, OPS is unique to Germany.

France[57]

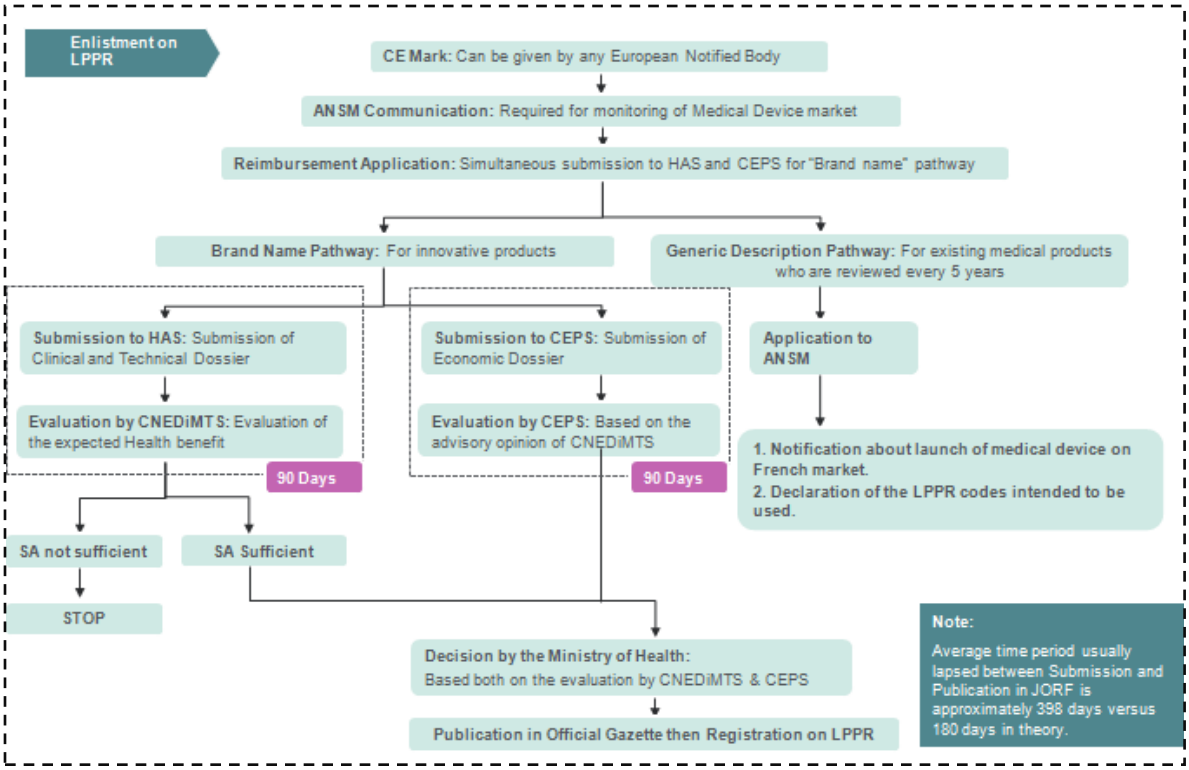
Reimbursement coverage pathway for medical device and procurement in France constitutes 3 pathways namely: DRG system, enlistment on LPPR and inclusion in medical procedures.



Adopted from: ispor

Figure 4.15: Reimbursement pathways for medical devices in France

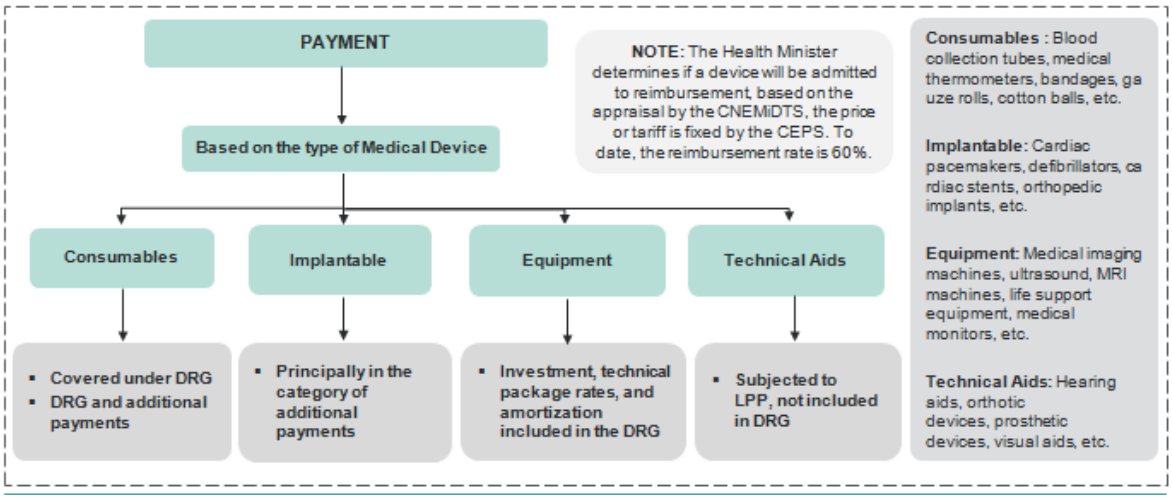
Enlistment on LPPR (*Liste des Produits et Prestations Remboursables):*



Adopted from: HAS

Figure 4.16: Enlistment on LPPR for medical devices in France for reimbursement

Payment process for medical devices in France[50]:

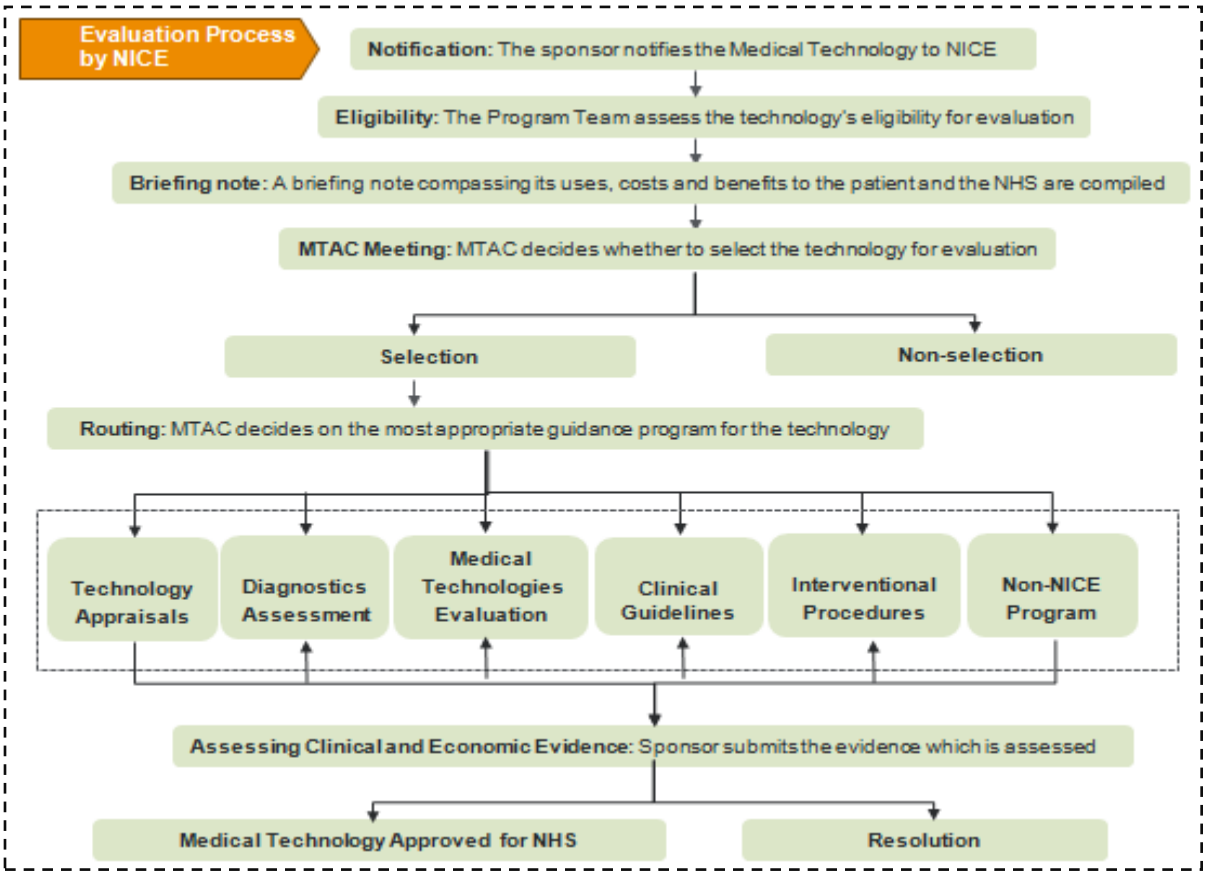


Adopted from: ncbi

Figure 4.17: Payment model for medical devices in France

U.K (United Kingdom)[58, 59]

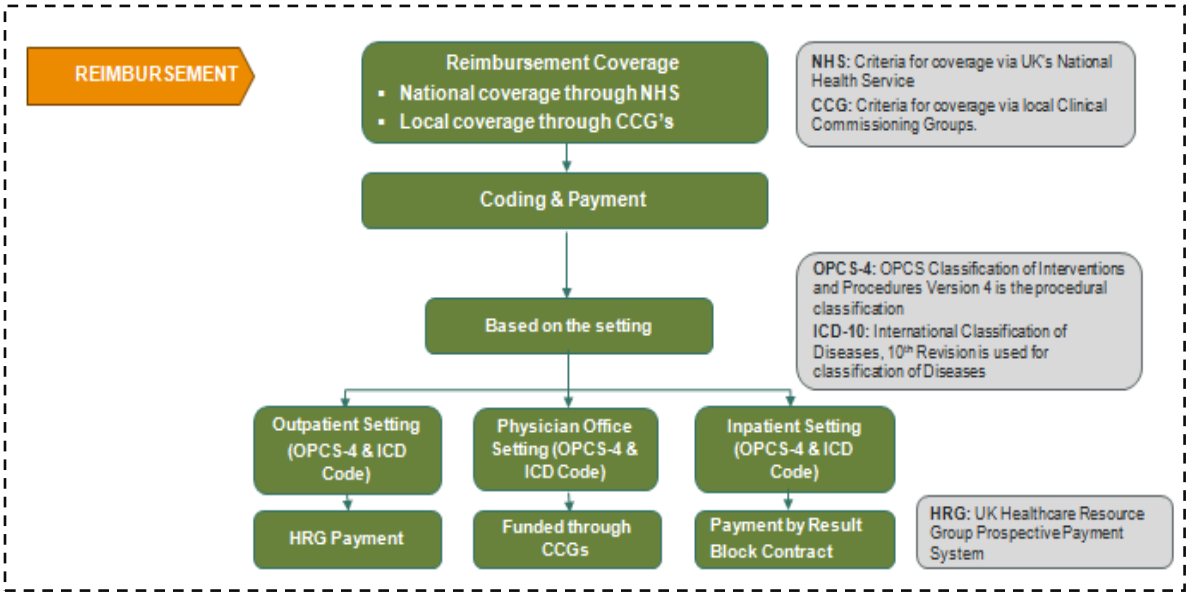
The evaluation process for medical devices in U.K by NICE to be included on the national formulary list:



Adopted from: NICE

Figure 4.18: Evaluation process for medical devices by NICE in U.K

Coverage, coding and payment model for medical devices in the U.K:



Adopted from: gov.uk

Figure 4.19: Overall reimbursement process for medical devices in the U.K

Payment mechanisms for medical devices in the U.K[51]:

i. **Payment-by Results (PBR)** – Is essentially a DRG system, to establish fixed prices for hundreds (now approximately 1400) of hospital procedures. The PBR system has been extended to cover treatments and procedures provided to patients as day cases or outpatients. Certain services are funded as "un bundled" payments in the latest payments schedule (HRG4) in order to allow different payments for different parts of the care pathway, e.g. diagnosis, treatment, rehabilitation, etc. Hence, the system of PBR, originally intended for paying for products and services used to treat inpatients may eventually be extended to provide prospective payments for a range of out-of-hospital services.

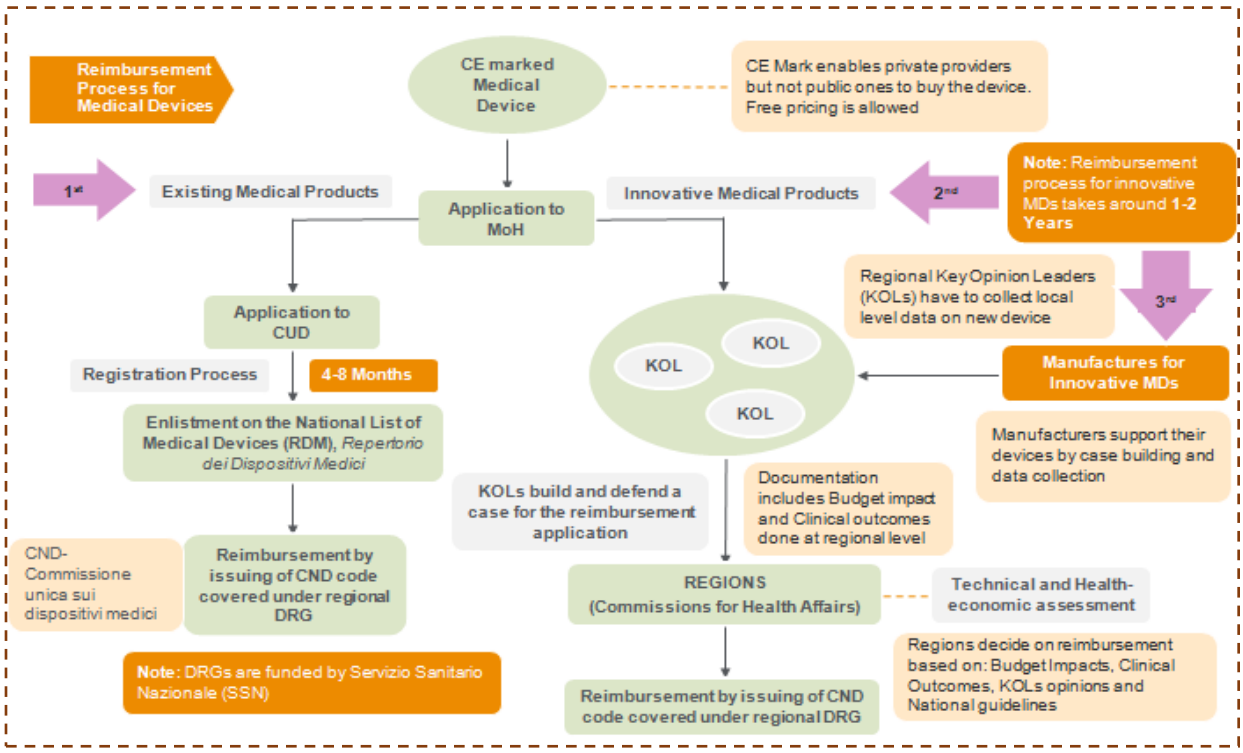
ii. **Block Contracts** – Are the agreements between care providers and PCTs (primary care trusts) to use and pay for a certain product or service.

iii. **Global Budgeting** – In this form of payment, healthcare providers can purchase products or services from their own budgets.

Italy

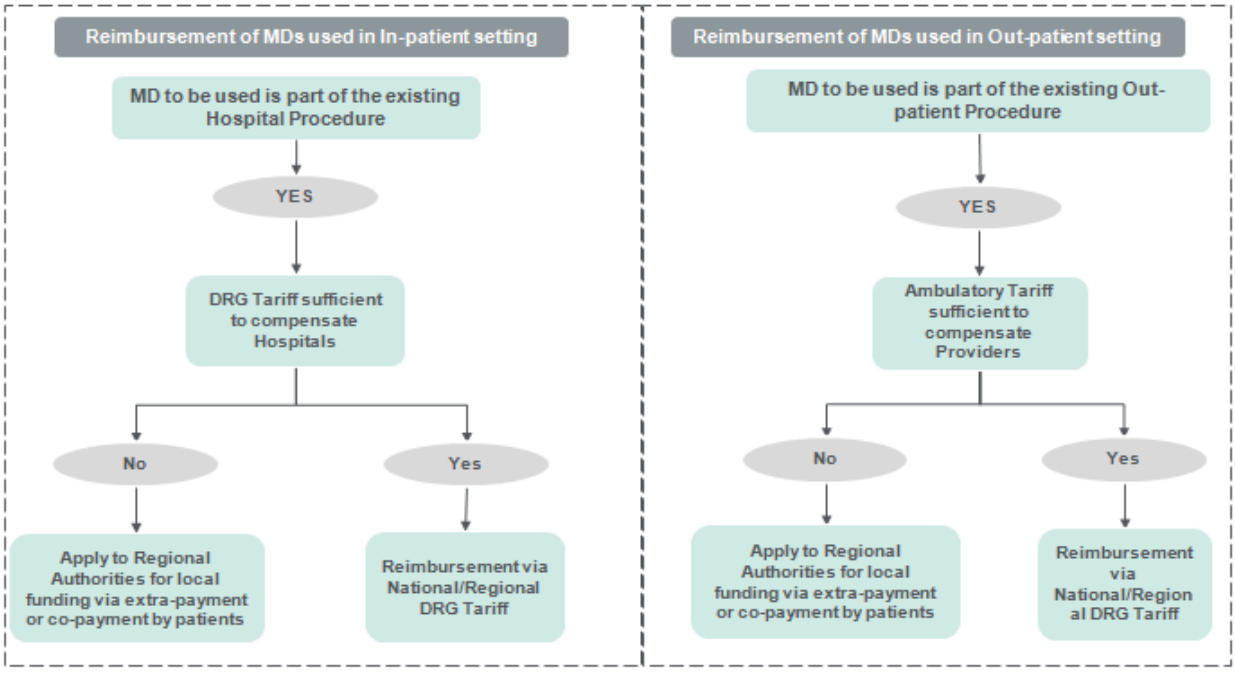
In Italy, pricing and reimbursement for medical devices is carried out at the regional level, with the funding and pricing provided by the national health coverage system.

Coverage and payment for medical devices in Italy[52, 60]:



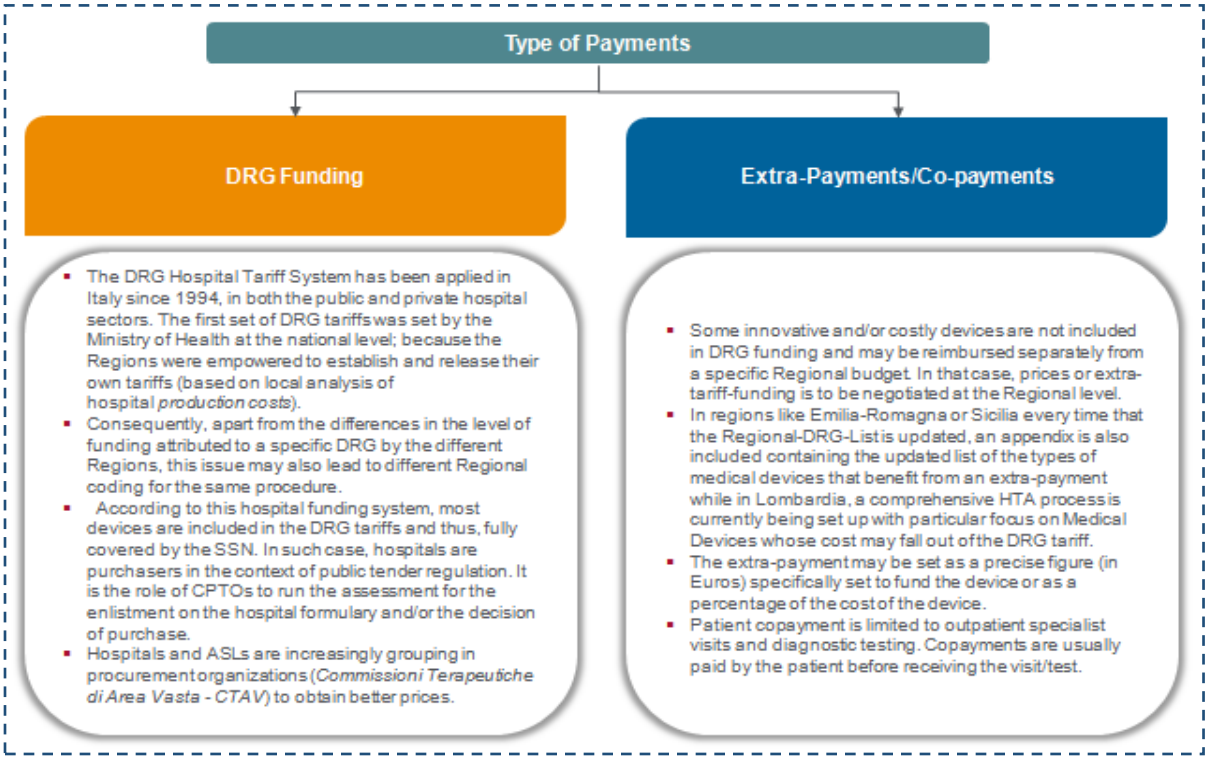
Adopted from: ncbi

Figure 4.20: Overview of reimbursement process of medical devices in Italy



Adopted from: ispor

Figure 4.21: Reimbursement for medical devices in Hospital setting in Italy

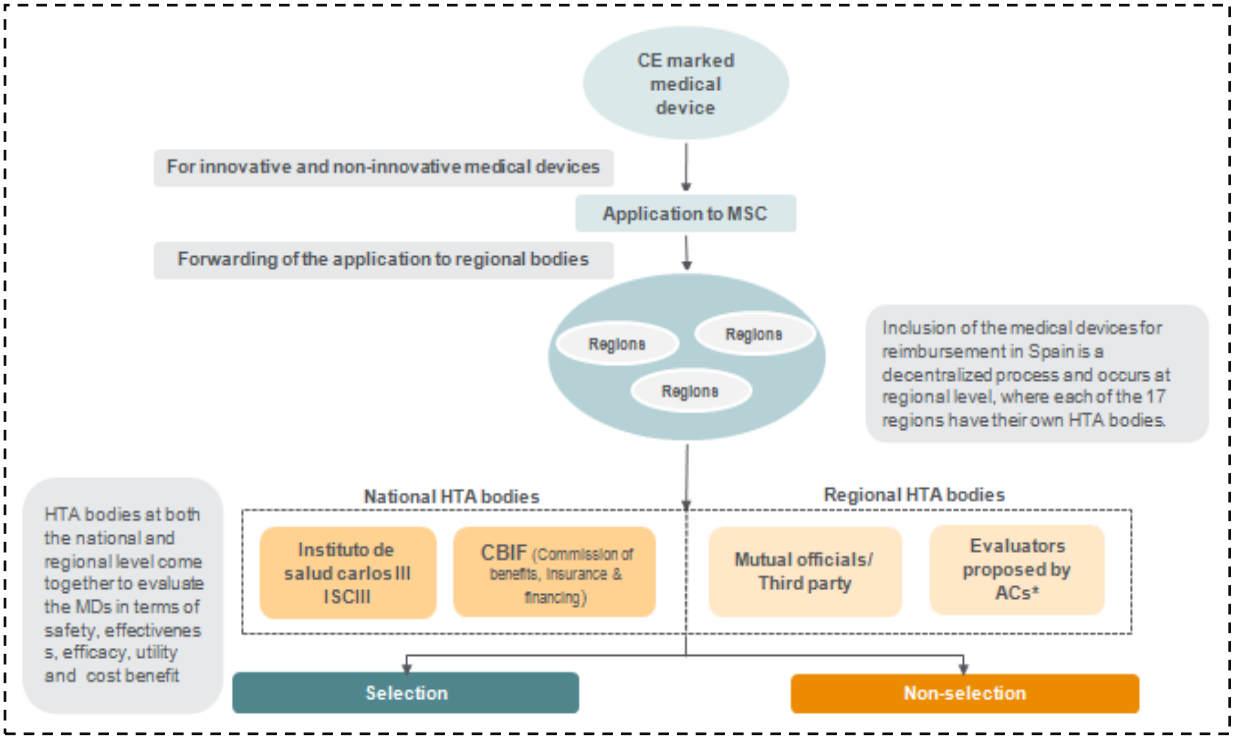


Adopted from: ispor

Figure 4.22: Payment models for medical devices in Italy

Spain

Coverage and payment of medical devices in Spain[61]



Adopted from: ispor

Figure 4.23: Overview of reimbursement process for medical devices in Spain

Coverage and payment decision making for medical devices under the reimbursement process in Spain are undertaken by regions referred to as Autonomous Regions and the payment is made at the national level by the Health Insurance bodies.

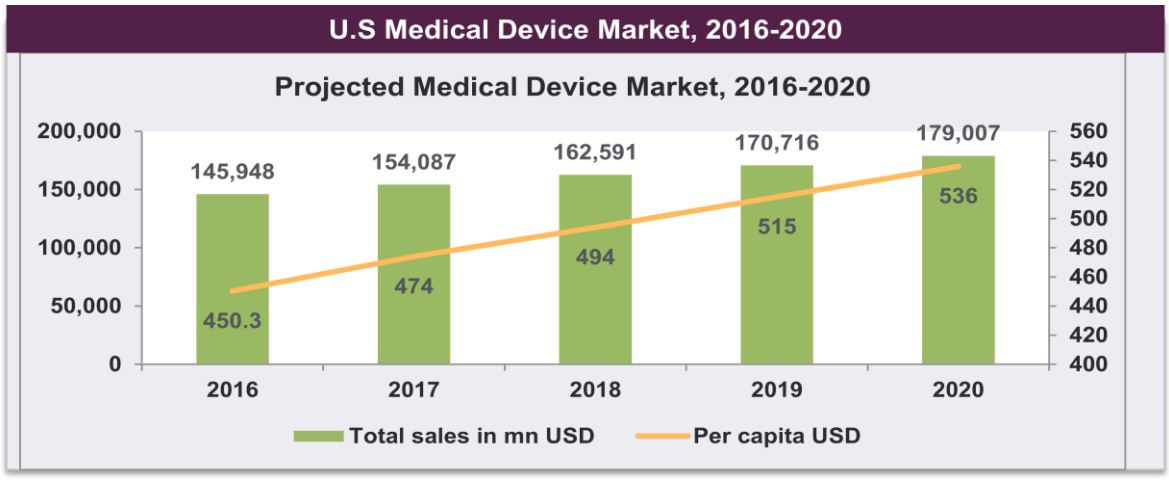
4.4 To study the emerging trends and their impact on the medical device sector in the USA and Europe

In order to identify and enlist the forthcoming or the existing trends in the medical device market in the USA and Europe, forces influencing and shaping the medical device industry based on consumer needs, demographics, epidemiology of diseases, different provider setting landscape, changing legislation, changes due to the dynamic administrative scenario like Trump's victory in USA and application of Brexit in EU, overall influences the medical device journey right from getting manufactured to being consumed/ used in the healthcare establishments.

4.4.1 Comprehensive overview of medical device market in both the geographies (U.S & EU-5)

A. *USA*

A.1 Current and forecasted medical device market size in the U.S [62]



Adopted from: BMI US Industry Report

Figure 4.24: U.S Medical Device Market, 2016-2020

The United States continues to be the largest medical device market in the world with a market size of around $145bn in 2016, and it is expected to reach $170bn by 2019. According to the US economic census 2012, the medical device industry employed more than 356,000 employees at over 5,800 establishments of which most of the companies are small and medium sized enterprises.

A.2 Industry drivers or barriers of the medical device market in the U.S[63]

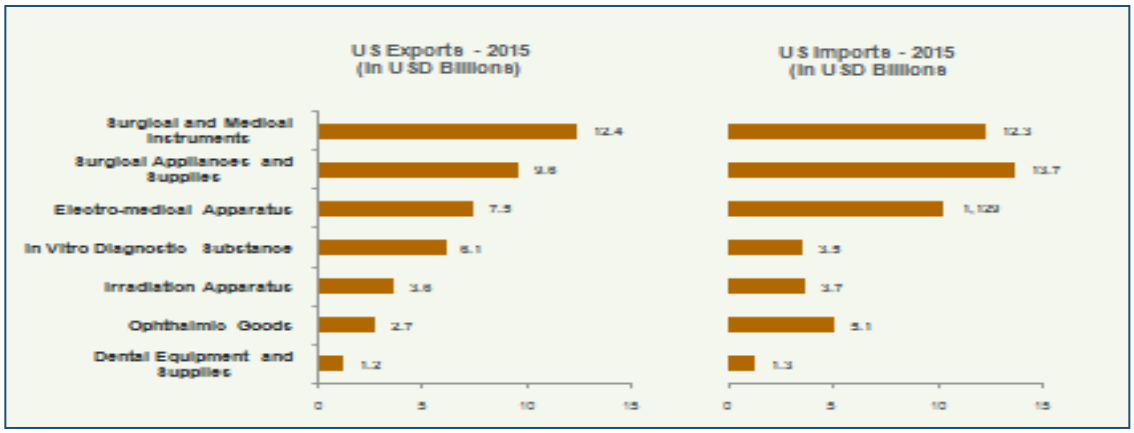
Industry Drivers

i. **Up surging Healthcare Market:** Increasing global demand because of lifestyle diseases, ageing population and increasing strive to improve the quality of life.
ii. **Government Policy:** Government policymakers are seeking to create new and sustained export opportunities for U.S medical device market.
iii. **Medical-technical Innovation:** Unprecedented advancement in innovative and developed technologies is leading to growth in the overall medical device industry.
iv. **Altering Provider setting:** Consolidation in healthcare with the rise of ACO's and GPO's has altered the medical device buying decisions.

Industry Barriers

i. **Government Policy:** Higher tax rates are being imposed by the government
ii. **Challenging Manufacturing Regulations:** Stringent regulations for device commercialization and distribution, trade (Export and Import), dynamic and highly evolving nature of regulations makes things difficult for the manufacturers.
iii. **Market Conditions:** Stringent labor laws, high operating costs.
iv. **Price pressures on medical device companies:** Different regulatory requirements, reduced reimbursements, higher tariffs in different countries impact the sales of medical devices.

A.3 Import-export market of U.S medical devices[63]



Adopted from: export.gov

Figure 4.25: U.S medical device trade report, 2015

i. Besides leading the world in the production of medical devices, the United States is the largest medical devices consumer.
ii. The surgical and medical instruments category represents the subgroup with the most activity in the United States.
iii. This category includes anesthesia apparatus, orthopedic instruments, optical diagnostic apparatus, blood transfusion devices, syringes, hypodermic needles and catheters.

B. *Europe*

B.1 *Germany*

B.1.1 Current and forecasted medical device market size in Germany

Table 4.1: Germany medical device market, 2015-2019

Germany Medical Device Market Size	2015	2015f	2016f	2017f	2018f	2019f
Total sales in mn Euro	21,830	22,931	24,340	25,759	27,263	28,916
Per capita in Euro	271	284	302	320	339	360

Adopted from: BMI report Germany

The medical device industry in Germany is mostly based on small and medium sized companies where, 95% of the companies have less than 250 employees. The industry is divided in 31% in auxiliary products, 24% implants, 23% surgical products, 18% wound care and 16% services and home care.

According to the association of medical devices BVMed, total sales of the German manufacturing medical device companies (with more than 20 employees) increased by 8.5% in 2015. This increase is due to increase in Germany, the weak Euro exchange rate, lower oil prices and an increase in demand from emerging markets.[49]

The market is expected to grow at a CAGR of 5.8% in Euro terms from 2015-2020.

B.1.2 Industry drivers or barriers of the medical device market in Germany

Industry drivers:

i. The medical-technical innovation in treating disease areas that were not able to be treated before.

ii. The demographic development in Germany to an older population.

iii. The extended meaning of the word health towards quality of life.

B.1.3 Import-export market of Germany medical devices [49]

German Medical device industry sales	2009	2010	2011	2012	2013	2014	2015
Total sales in bn Euro	20.0	21.7	23.2	24.1	24.6	25.4	27.6
Sales in Germany in bn Euro	7.5	7.8	7.8	7.7	7.9	9.0	10.0
Sales outside of Germany in bn Euro	12.5	13.9	15.4	16.4	16.7	16.4	17.6

Germany's top 10 countries for medical device import (in mn Euro)	2015	2013	2011
US	3,922	3,232	2,824
Switzerland	1,706	1,531	1,219
China	917	681	523
Japan	708	677	651
Netherlands	594	521	544
UK	575	460	417
France	566	577	576
Ireland	513	399	301
Mexico	445	322	260
Poland	392	308	178

Adopted from: expo.gov

Figure 4.26: Export-import market for medical devices in Germany

i. Germany's global share of medical device export is of 14.6%, which makes it number two after the US (30.9%).

ii. Despite the US being the most important export destination for German medical device manufacturers and despite the increasing demand from China, Europe is the number one export destination for the German medical device industry. 41% of exports go into EU countries, 10% in the rest of Europe, 18% exports to US and 18% exports to Asia.

iii. Number 1 import destination is the United States. US is followed by Switzerland and China and Japan.

B.2 *France*

B.2.1 *Current and forecasted medical device market size in France*

Table 4.2: France medical device market, 2015-2020

France Medical Device Market Size	2015	2016	2017f	2018f	2019f	2020f
Total Market Size (Local Currency mn)	11,699.3	12,354.2	12,856.2	13,385.3	13,959.8	14,558.6
Per capita (Local Currency mn)	181.7	191.0	198.0	205.3	213.2	221.5

Adopted from: BMI REPORT

In 2016, medical device market in France is the second largest in Europe after Germany, and fifth largest in the world. It is expected to remain the fifth largest market in the world and will see more moderate growth in the next five years. It is forecasted to rise by a CAGR of 4.5%. At present, there are nearly1,100 medical device manufacturers mainly established in the Paris, Lyon and Strasbourg regions of France. 73% of these companies, which employ 65,000 people in total, are French businesses whereas the remaining 27% of companies are foreign subsidiaries of American, German, Swiss and Japanese origin.[64]

Medical device manufacturers majorly comprise of small and medium scale enterprises enrolling less than 250 employees, of which 45% have less than 20 employees. Medical device companies in France are particularly active in the field of single-use devices, which represents almost two thirds of national turnover. Manufacturers have gained strong expertise in the field of implants (prostheses), technical support, minimal-invasive surgery systems, diagnostic imaging and in vitro diagnostics.[65]

B.2.2 Industry drivers or barriers of the medical device market in France

Industry drivers

i. Shift of focus from diagnostic to preventive care.
ii. Demographic shift to older population and increasing incidence of chronic and lifestyle diseases in France.
iii. Increasing technical innovations in the field of healthcare.
iv. More demand for self-monitoring, minimally invasive devices with increased demand for home-based treatment.[65]

B.2.3 Import-export market of France medical devices

Table 4.3: France export-import market for medical devices, 2014-2017 [66]

France Medical Equipment* Export-Import Market	2014	2015	2016f	2017f
Total Export (USD mn)	2500	2575	2652	2732
Total Import (USD mn)	3713	3824	3928	4038

Source: expo.gov

i. France's export segment of medical device industry is estimated to be valued at around 6.845 Billion Euro while the import segment is valued at 9.436 Billion Euro.

ii. France ranks ninth amongst the top ten export countries because of the size of its medical device market for exports in 2016 by the US Department of Commerce.

iii. With flagging domestic production in several sectors the French medical device market is increasingly reliant upon imports, which now account for around 50 percent of consumption in 2015.

iv. Orthopedic and prosthetic devices are expected to continue to be the most dynamic sector of the market.

B.3 U.K (United Kingdom)

B.3.1 Current and forecasted medical device market size in the U.K

Table 4.4: U.K. medical device market, 2015-2020

U.K Medical Device Market Size	2015	2016	2017f	2018f	2019f	2020f
Total Market Size (Local Currency mn)	7,175.7	7,393.6	7,601.6	7,869.7	8160.0	8481.4
Per capita (Local Currency mn)	110.9	113.6	116.0	119.4	123.1	127.2

Source: BMI REPORT

The U.K medical device market is the third largest in Europe and sixth largest in the world. It is expected to rise by a CAGR of 3.5%.

There are approximately 3,100 medical manufacturers in the UK, employing about 71,000 people. Domestic device manufacturing is characterized by around 2,000 companies which

comprise of small and medium scale medical device companies alongside a few global manufacturers with a significant presence in the market.[67]

More than 500,000 technologies are available in U.K medical device market. The strength of UK manufacturers lies, especially in orthopedics but also in imaging, diagnostics, and cardiovascular devices.

B.3.2 Industry drivers or barriers of the medical device market in the U.K

Industry drivers[68]

i. Demographic shift towards older population in the U.K.

ii. More technical innovations in the field of healthcare.

iii. Increasing demand for self-monitoring and minimally invasive devices.

iv. Approvals for medical devices are faster in the U.K with long term revenue streams.

B.3.3 Import-export market of U.K medical devices

Table 4.5: U.K export-import market for medical devices, 2014-2017[69]

U.K Medical Device Export-Import Market	2014	2015	2016f	2017f
Total Export (USD mn)	5,282	5,421	5,561	5,635
Total Import (USD mn)	6,384	6,469	6,432	6,595

Source: expo.gov

i. U.K's export market for medical device industry is financially estimated to be valued at around 5.614 Billion Euro while the import market is valued to be around 7.834 Billion Euro in the year 2015.[67]

ii. The medical device trade is export-led, as most domestically manufactured products are exported to other markets.

iii. As the majority of domestically produced medical products are exported hence, there is increased demand for imports. The U.S. is an important overseas source of medical devices with an estimated 19% share of the market. It is a leading supplier of diagnostic, dental, orthopedic equipment and high quality wound care products to the UK.

B.4 *Italy*

B.4.1 Current and forecasted medical device market size in Italy

Table 4.6: Italy medical device market, 2015-2020 [70]

Italy Medical Device Market Size	2015	2016	2017f	2018f	2019f	2020f
Total Market Size (Euro mn)	7859.7	8015.8	8250.5	8461.5	8692.2	8948.9
Per capita (Euro mn)	131.4	134	138	141.5	145.5	149.8

Source: BMI REPORT

In 2016, Medical Device market in Italy was the fourth largest in Europe with a forecasted CAGR of 2.6% from 2015-2020. According to the BMI Report 2017 Italy is expected to remain fourth largest market in Europe.

In Italy (2015) there are 4,480 majorly small to mid sized companies active in the field of medical devices generating an average turnover of 5 Million Euros of which 52% are manufacturing companies, 44% are commercial companies and remaining 4% are service companies. 41% of multinational companies are Italian based while 59% are foreign based. The Italian medical device industry employs over 70,000 persons with 22,500 working for foreign-owned companies

Due to the highly active medical technology hot spots in Lombardy and Emilia-Romagna, the northern (17%) and central (10%) regions host the largest portion of multinational companies while southern regions (2%) house negligent number of companies.

Most companies are active in the areas of biomedical research (44.5%) and biomedical instruments (20.4%) together generating 59.2% of industry turnover with IVD (6%) forming a small but active segment of the overall industry generating almost 12% of the industry turnover.

B.4.2 Industry drivers or barriers of the medical device market in Italy

Industry drivers

i. Strong Start-up culture: As of June 2016, there were 328 start-ups active in Italy with IVD sector (26%) being most popular.
ii. Innovative and mature Italian medical device market with strong emphasis on local production.

Industry barriers

i. Medical device market growth will be restricted with a sluggish economy and healthcare cost-containment measures in the coming years.

B.4.3 Import-export market of Italy medical devices[71]

Italy Medical Devices and Equipment Market	2014	2015	2016f	2017f
Total Export (USD mn)	4,200	4,275	4,328	4,405
Total Import (USD mn)	6,580	6,698	6,528	6,645

Italy's top countries for MD Export	2014 (Million Euros)	Italy's top countries for MD Import
US	993.4	Netherlands
France	747.7	Germany
Germany	584.8	Belgium
Spain	389.3	France
UK	315.1	US

Source: expo.gov

Figure 4.27: Italy export-import market for medical devices, 2014-2017

i. Italian export of medical devices totaled 7 Billion Euros in 2015, up by 8.1% from the previous year with an increase in all the segments with most dynamic being Biomedical sector who has been amounted to 4.4 Billion Euros.

ii. Imports, in turn, amounted to 7.3 Billion Euros in 2015, an increase of 6% over the previous year with significant increases in Biomedical Instrument (10.2%) and Biomedical (5.9%) sector.

B.5 *Spain*

B.5.1 *Current and forecasted medical device market size in Spain*

Table 4.7: Spain medical device market, 2015-2020 [72]

Spain medical device market size (excl. services)	2015	2016	2017f	2018f	2019f	2020f
Total market size (Euro mn)	4,388	4,449	4,589	4,701	4,893	5,155
Per capita (Euro mn)	95	97	100	102	106	112

Source: BMI REPORT

The medical device market in Spain is the fifth largest in Western Europe and ninth largest in the world (2016).

Spain's medical device sector is made up of 720 companies of which 520 companies are manufacturering with 23,000 workforce. Small and medium sized companies make up 92% of the market (40% turnover), while large companies account for 8% market. Strength of Spain's manufacturers lies in IVD, diabetic care, single-use, orthopedic, cardiovascular and ophthalmic devices[73]

B.5.2 Industry drivers or barriers of the medical device market in Spain

Industry drivers

i. The demographic shift in Spain to the older population (17% of the population aged over 65 years).

ii. Increased prevalence of chronic and lifestyle based diseases.

iii. Digital transformation in the field of medical devices.

iv. Increased demand for innovative, self-monitoring and minimally invasive technologies.

Industry barriers

i. Unstable political environment.

ii. Application of cost-containment measures in the health sector.

B.5.3 Import-export market of Spain medical devices

Table 4.8: Spain export-import market for medical devices, 2014-2017 [74]

Spain Medical Equipment Export-Import Market	2014	2015	2016f	2017f
Total Export (USD mn)	2928	2591	2724	2833
Total Import (USD mn)	6489	5600	5864	5900

Source: expo.gov

The Spanish healthcare sector continues to rely heavily on imports, with countries of EU like Germany, Italy, France and US as major sources of import.

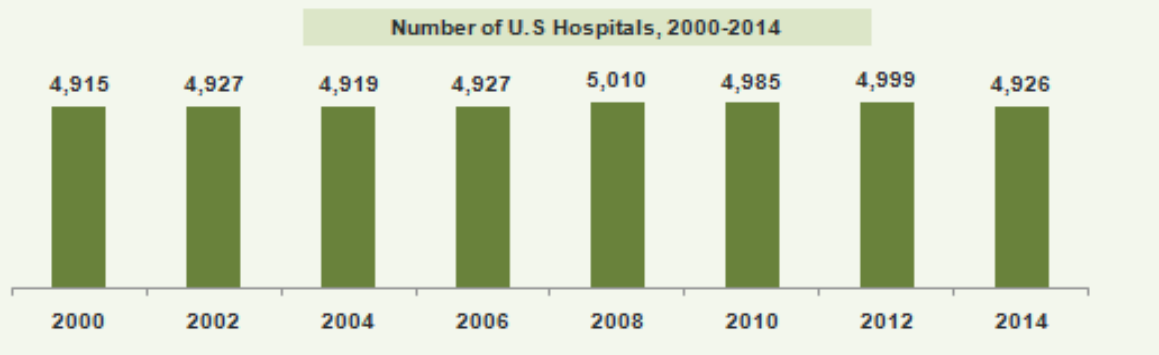
4.4.2 Overview of the provider setting landscape (healthcare establishments) and its indices in both the geographies (US and EU-5)

Provider setting refers to all the healthcare establishments which are responsible for disseminating preventive, promotive, curative and other services to the patients. Changing dynamics in these healthcare bodies in term of changing reforms, the number of establishments, etc. directly or indirectly affects the medical device sector.

A. *USA*

A.1 Healthcare providers and indices through the years

Decrease in the number of hospitals[75]



Source: AHA Report

Figure 4.28: Number of hospitals in U.S, 2000-2014

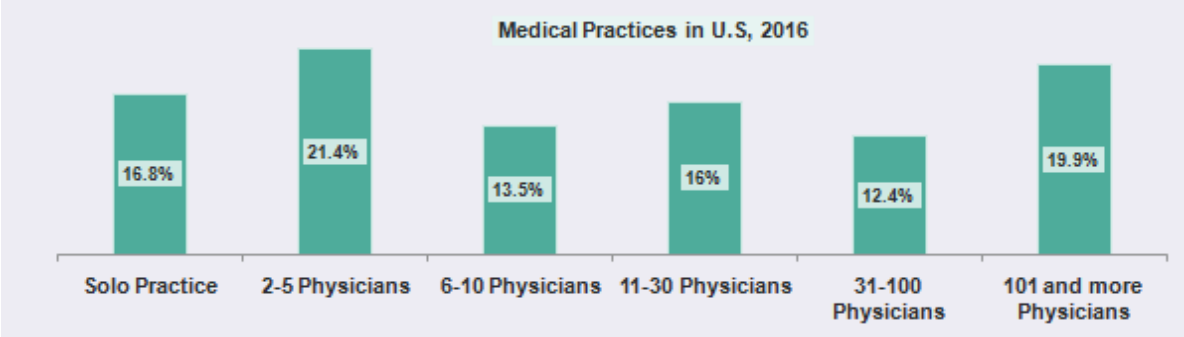
The hospital industry in U.S includes operators licensed as general, medical, and surgical hospitals that provide surgical and nonsurgical diagnostic and medical treatment to inpatients and outpatients with medical conditions. The number of hospitals have seen a consistent decrease through the years and it is estimated that one-third hospitals will close by 2020 due to the structural and healthcare changes in the U.S.

Independent hospitals are confronting a period of rapid change by considering a variety of partnerships and collaborations with other hospitals to improve clinical and financial performance. Some are actively affiliating with larger systems like IDN's while others are remaining independent, but engaging in more partnerships with regional hospitals. Alternative Business deals like partnerships, strategic alliances, Affiliations, JVs are trending up.

This as a result is giving more bargaining power to the hospitals and other healthcare providers in terms of **better pricing** results with the manufacturers of medical devices.

Decrease in the number of physician's solo practices

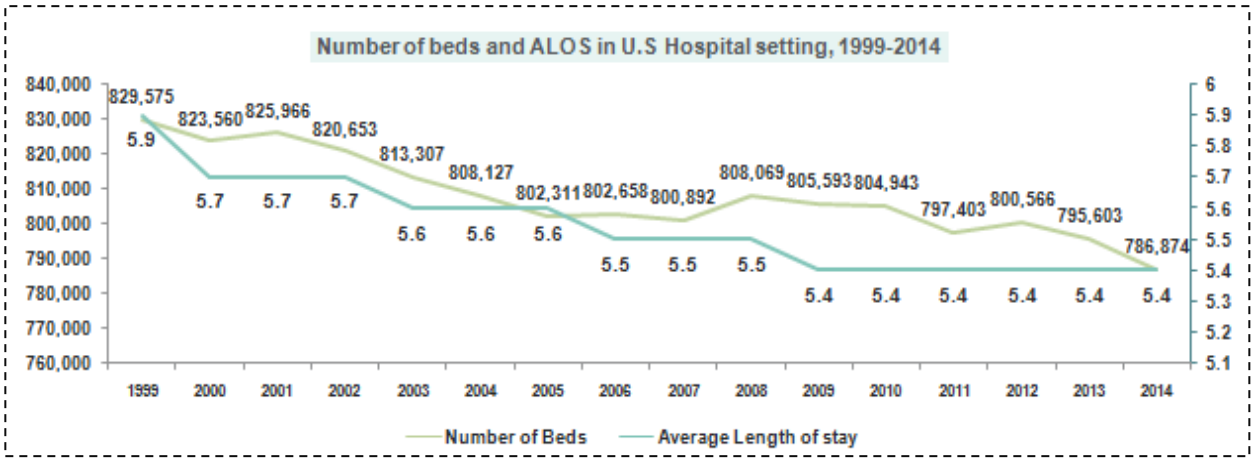
Emergence of managed care has caused physicians to seek out new models of health care delivery to cope up with the new regulations and to be more cost effective. The new business model offers joining together of physician practices in ways that offer autonomy, but no subordinating their interests to the interests of hospitals. Physicians are pursuing a strategy of equity independence, are partnering with other physicians, and are positioning themselves and their newly formed organizations in the healthcare market (Statistica, 2016).



Source: Statistica

Figure 4.29: Number of solo practices in U.S, 2016

Decrease in number of beds and average length of stay in U.S hospitals[75]***:***



Source: AHA report

Figure 4.30: Number of beds and ALOS in U.S hospitals, 1999-2014

There has been a consistent decrease in the number of hospitals and ALOS through the years in the U.S. Key challenges in present scenario for hospitals and physician practices is to implement cost-containment measures, i.e. reduce hospital stay, improve quality of

services being provided, reduce emergency room visits and expensive specialist and testing services, which are the major business strategy in the current fee-for-service system.

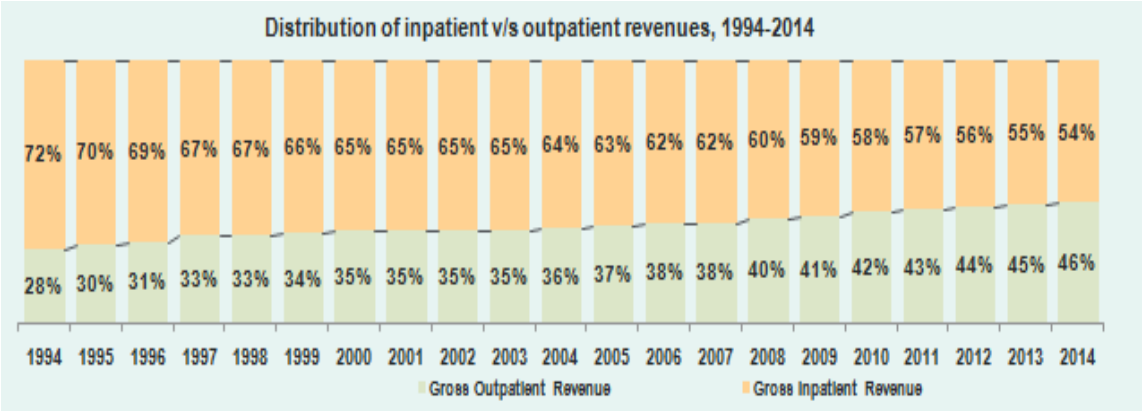
Number of beds have decreased due to the decline in the number of hospitals and increasing gravitation towards out-patient procedures in the recent years.

The average length of stay in hospitals (ALOS) is often used as an indicator of efficiency in the healthcare setting. A shorter stay will reduce the cost per discharge and shift care from inpatient to less expensive post-acute settings.

Shifting health care dynamics towards out-patient settings in the U.S

Key reasons for shift from in-patient to out-patient Settings:

i. Minimally invasive surgeries being favored in recent years.
ii. Pricing pressure favoring low cost of outpatient settings due to low overheads.
iii. More focus on preventive health care and keeping patients out of the hospitals.
iv. Due to favorable reimbursement rules and payment models for outpatient settings.



Source: AHA report

Figure 4.31: Inpatient v/s outpatient revenue in U.S, 1994-2014

Shift in healthcare dynamics to out-patient settings has consequently shifted focus of medical device manufacturers towards this sector of healthcare. Minimally invasive surgical medical devices are gaining strength in U.S healthcare[75].

B. *Europe*

B.1 *Germany*

B.1.1 Healthcare providers and indices through the years

Decrease in the number of hospitals [76]

Source: Destasis

Figure 4.32: Number of hospitals in Germany, 2003-2015

The number of hospitals has continuously decreased from 2,197 in 2003 to 1,956 in 2015 in Germany. The reason behind this is the increased consolidation amongst the hospitals and increase in the number of out-patient centers and long-term stay structures in Germany due to the demographic shift towards elderly population, thereby closing down of the redundant healthcare structures.

This increased consolidation amongst the healthcare structures has also consequently increased their bargaining power, thereby resulting in better pricing results when negotiating with the medical device manufacturers. Also, there is increased incidence of evidence based purchasing of medical devices in Germany resulting in increased pressure on the medical device manufacturers to deliver better.

Decrease in average length of stay in German hospitals[76]

Source: Destasis

Figure 4.33: ALOS in Germany, 2003-2015

The length of stay also has decreased from 8.9 days in 2003 to 7.3 days in 2015. It has happened because of the increase of day clinics and the increasing importance of out-patient surgeries in the healthcare sector. The hospital bed utilization is 77.5% in 2015.

For medical device manufacturers it means focusing on the out patient sector of healthcare in Germany, especially in the minimally invasive devices used majorly in the out patient settings.

Increased number of nursing home facilities in Germany[76]

2.63 million people in 2013 were in need of long term care (+ 5% compared to 2011). The number of nursing home chains is expected to increase, according to a survey done with nursing home operators. This will improve negotiation power for medical product procurement.

Year	No. of nursing homes	No. of ambulatory nursing services
2005	10,424	10,977
2007	11,029	11,529
2009	11,634	12,026
2011	12,354	12,349
2013	13,030	12,745

Source: Destasis

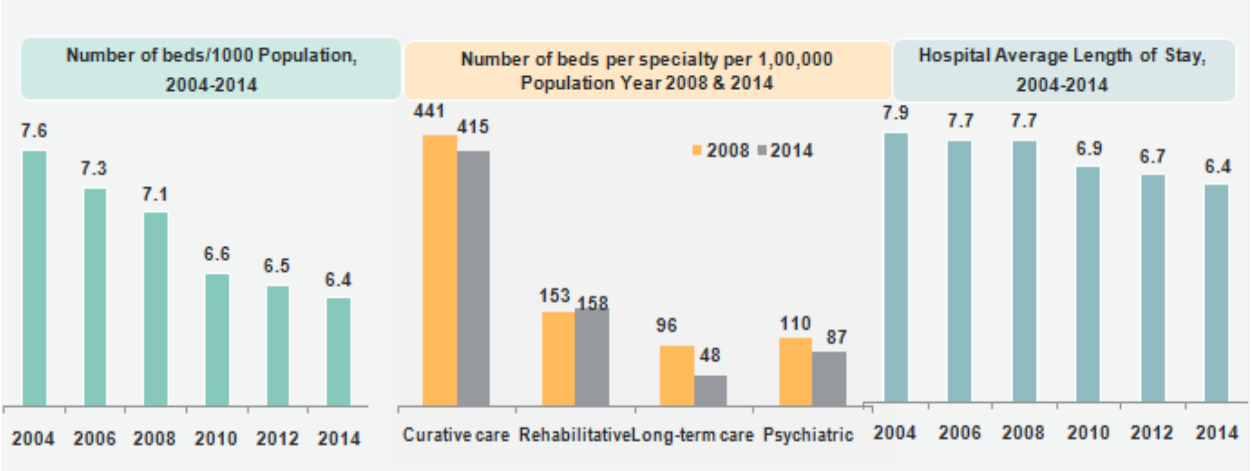
Figure 4.34: Number of nursing homes in Germany, 2005-2013

This increase in long term facilities in Germany has opened a new market for medical device manufacturers in this sector.

B.2 *France*

B.2.1 Healthcare providers and indices through the years

Decrease in the number of hospital beds and in-patient discharges[77]



Source: OECD Database

Figure 4.35: Overview of inpatient setting in France.

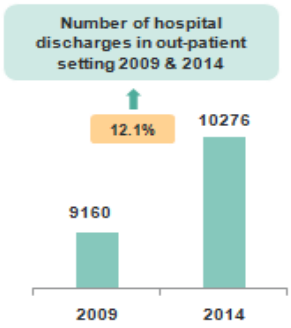
Consistent with the general trend in Europe the number of hospitals and hospital beds in France have declined over the years. Between 2003 and 2011, the number of full-time hospital beds fell from 468 000 to 414 000.

The reduction in hospital capacity was most significant with respect to long-term care beds, which decreased by 40% between 2003 and 2011 through the transformation of certain units into nursing homes.

In France, ALOS is 6.4 days (2014) with bed occupancy of 75.8% (2013).

This increase in long-term care facilities in France has opened a new segment of interest for medical device manufacturers[78].

Increase in out-patient activities in France[78]



Increase in out-patient settings (2011):

- +17% growth in public sector
- +22% growth in non-profit making private sector
- +11% growth in profit making private sector

Day-care provision by healthcare sectors	Day-care beds	Day-care surgeries
Public Sector	50%	42%
Private profit-making	40%	50%
Private non-profit making	10%	8%

Source: Health in Transition

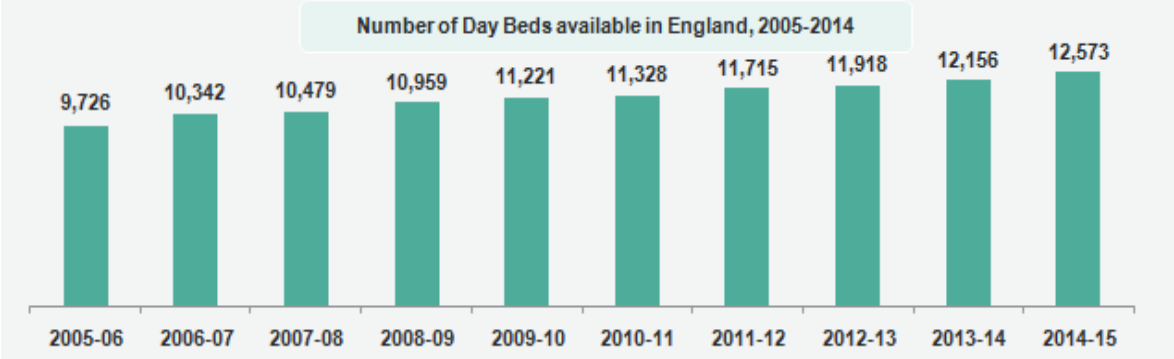
Figure 4.36: Overview of inpatient setting in France

Up surging outpatient setting in the healthcare sector has deviated medical device manufacturers' interest from inpatient to outpatient segment in French health care.

B.3 *U.K*

B.3.1 Healthcare providers and indices through the years

Increase in number of out-patient beds in the U.K[79]



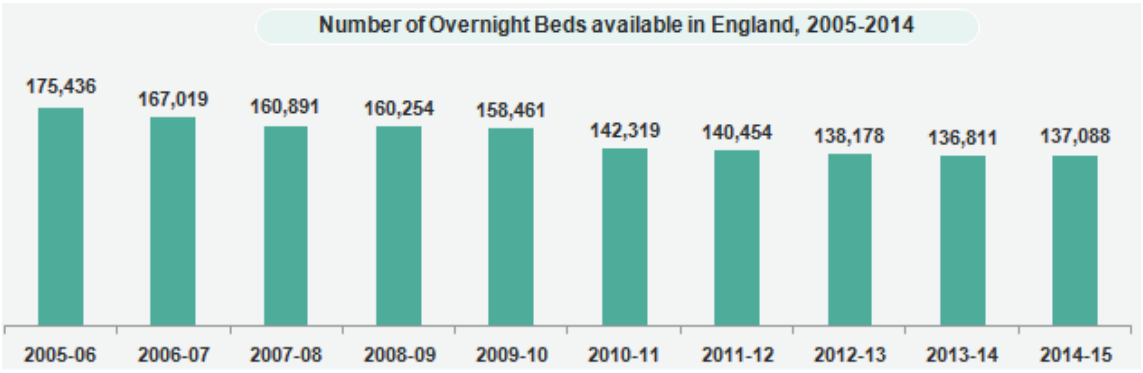
Source: Nuffield

Figure 4.37: Number of day beds in England, 2005-2014

The number of outpatient appointments has nearly doubled since 2005-06, rising from 60.6 million appointments to 113.3 million in 2015-16. The number of day-only beds have risen as more procedures are carried out as day cases and no longer requires an overnight stay due to the rapid increase of minimally invasive technologies in the healthcare market.

Again, this is providing an opening to the medical device manufacturers to venture out in this segment in the U.K health care.

Decrease in number of in-patient beds in the U.K[79]



Source: Nuffield

Figure 4.38: Number of overnight beds in the U.K, 2005-2014

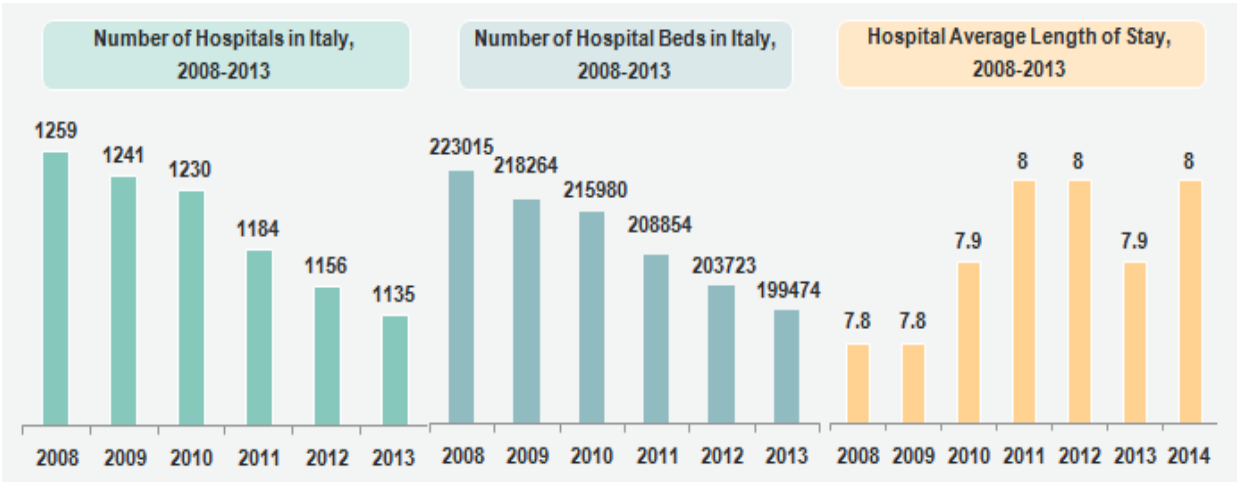
The number of overnight beds has decreased in the U.K health care system over time. The bed occupancy rate in 2104/15 has remained relatively steady between 84 to 89%, even thought he number of overnight beds have decreased steadily over time.

There has been an average trend in the Average Length of Stay (ALOS) from 7 days in 2005-06 to 5 days in 2015-16. Improvement in techniques and consequent reduction in the recovery time is the reason behind reduced ALOS. Though there has been a shift from in-patient to out-patient procedures over time, there is still lot of potential to be reaped from this sector in the U.K healthcare.

B.4 *Italy*

B.4.1 Healthcare providers and indices through the years

Decrease in hospitals, hospital beds and ALOS in Italy[77,78]



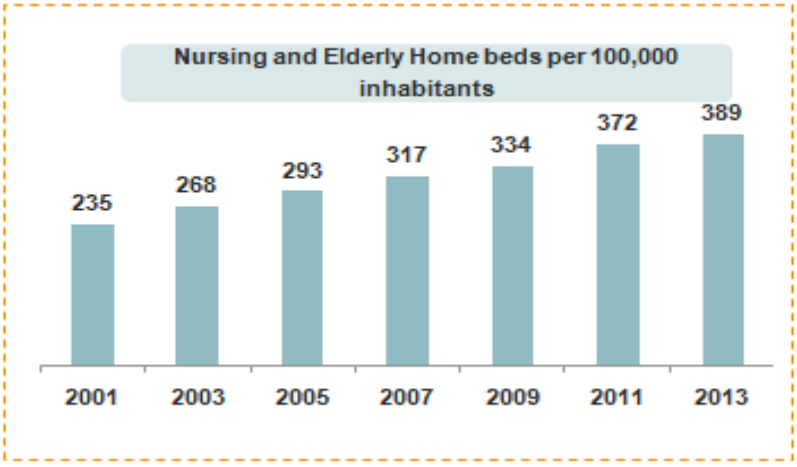
Source: OECD Data

Figure 4.39:Overview of the Italian healthcare provider sector

The number of hospitals has continuously decreased from 1259 in 2008 to 1135 in 2013 following the general trend in Europe. Consistent with another trend in Europe, the number of beds in Italy has declined from 2,23,015 to 1,99,474 particularly acute hospital beds from 258 beds/100,000 population (2008) to 237 beds/100,000 population in 2013. This is accounted to the increasing importance of outpatient procedures and shift in admissions to day hospitals and ambulatory care along with gravitation towards home and domiciliary care for the elderly requiring long-term care.

Average Length of Stay has almost remained constant from 2008 to 2014. The hospital bed utilization as of 2013 is 77%.

Increase in long-term care facilities



SOURCE: WHO

Figure 4.40: Nursing and elderly home beds, 2001-2013

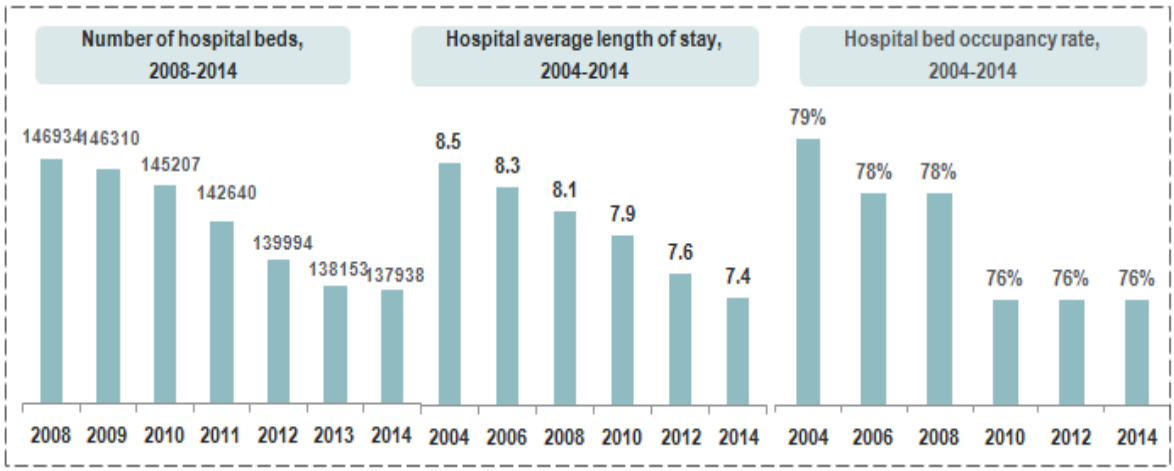
Long term care facilities like residential, semi-residential institutes and nursing homes provide long term elderly care (70.37%), psychiatric care (12.4%), terminal patient assistance (0.94%), psychic disability assistance and physically handicapped assistance (16.3%) in Italy. These long term health facilities are expected to blossom in the coming years due to increasing rise of the elderly population and upcoming policies to reduce the inpatient admissions.

This trend will influence negotiation power for medical product procurement and has opened a new segment for medical device manufacturers.

B.5 *Spain*

B.5.1 Healthcare providers and indices through the years

Decrease in the number of hospitals beds, ALOS and bed occupancy rate[77, 78]



Source: OECD Data

Figure 4.41: Overview of Spanish healthcare sector

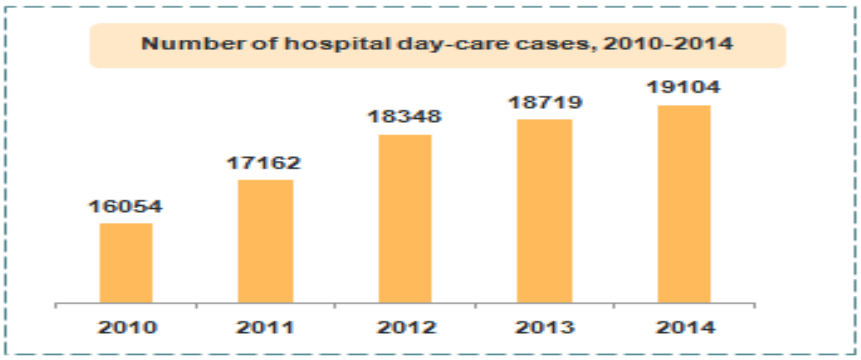
Consistent with the trend in Europe, the number of beds in Spain has declined over time, particularly acute hospital beds from 258 (2008) to 237 (2014) beds per 100,000 population & long-term care beds from 60 (2008) to 56 (2014) beds per 100,000 population in hospitals. This is due to the progressive introduction of day- hospitals and ambulatory care centers along with gravitation towards home and domiciliary care for the elderly requiring long-term care.

Average length of stay has declined from 8.5 (2004) to 7.4 (2014) days due to performance based incentives introduced in the Spanish healthcare system.

The hospital bed utilization has decreased over the years, probably owing to increased day-care admissions and therefore lesser need of hospitalization

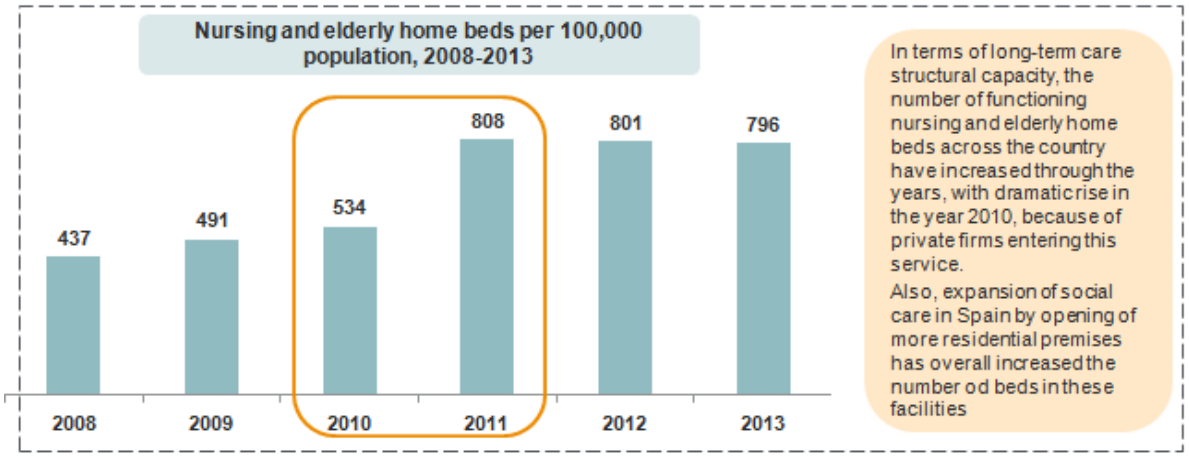
Increase in number of daycare cases

There has been a paradigm shift to out-patient cases in the Spanish healthcare system, this has blossomed the interest of the medical device manufacturers in this segment.



Source: WHO **Figure 42: Number of hospital day care cases, 2010-2014**

Increase in long-term and elderly care facilities



SOURCE: WHO

Figure 4.43: Nursing and elderly home beds per 100,000 population, 2008-2013

Spain's long term care facilities are segregated into facilities for elderly between 65 to 79 years old (59,527) and facilities catering to elderly people older than 80 years (1,62,994) from 2008. Long term facilities include residential homes (208,202), homes for disabled if 65+ (4,405) and nursing homes (9,914) according to data from 2008. These long term health facilities are expected to increase in the coming years due to rise of the elderly population and increased involvement of the private sector in this field.

This increasing tend will influence negotiation power for medical device procurement in this sector.

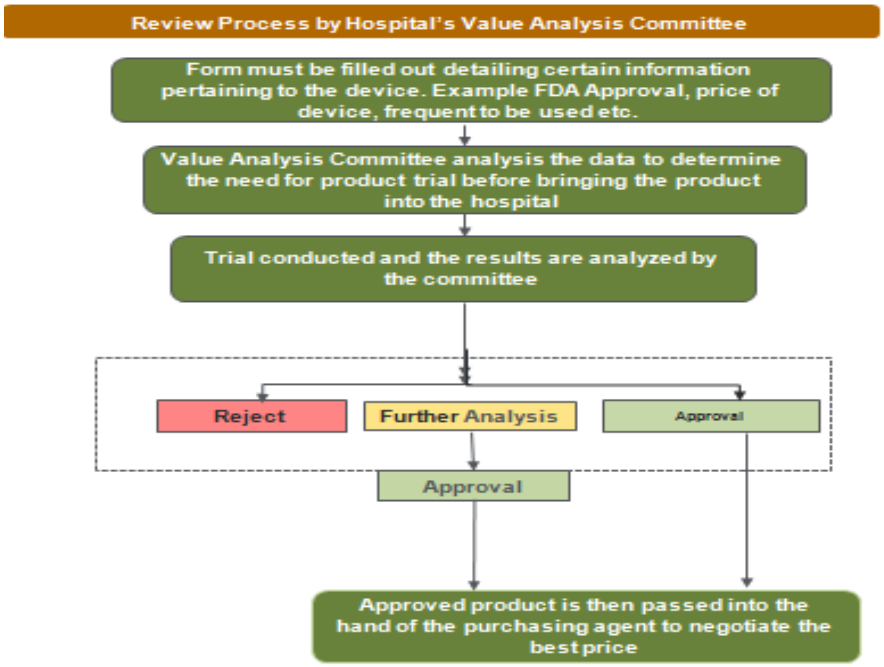
4.4.3 Overview of the decision makers involved in the procurement procedure for medical devices by healthcare establishments of each geography

Procurement procedure for medical devices followed in each geography, keeping into account the various decision-makers involved and the amount of leverage they have in taking the final call is.

A. *USA*

Decision makers involved in the medical device procurement procedure in the U.S healthcare establishments.

1. **Hospital based Analysis Committees:** Emergence of new reimbursement initiatives by CMS and strengthening of "value based purchasing" in hospitals has led to formation of analysis committees in U.S Hospital settings. These committees also referred to as "Value Analysis Committee" or "Technology Analysis Committee" have become an integral part of U.S provider setting and are becoming central in the decision making process for device procurement. It takes purchasing decisions with inputs from physicians/nurses in the said healthcare establishments. This committee is comprised of physicians/nurses, administrators, supply chain management, purchasing agents, liability specialist.



Source: Becker's Revie **Figure 4.44: Review process of medical devices by VACs**

2. **Procurement Groups:** Communities like GPO (Group Purchasing Organizations), ACO (Accountable Care Organization) and IDN (Integrated Delivery Network) are the entities that helps healthcare providers realize efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers and distributors. In general, procurement communities promise hospitals better pricing results.
3. **Hospital procurement department/Administration:** Takes purchasing decisions with inputs from physicians/nurses. Depending on the hospital, medical device departments also sometimes have a yearly budget for procurement of smaller investments.
4. **Physician/Nurse:** Previously they had the final call in buying the medical devices. However, in recent years their say has declined due to the increased evidence based purchasing by the healthcare establishments.
5. **Payers:** Few patients are able to pay for health care directly, hence third-party payers play an influential role in influencing medical device department. Medical device manufacturers depend on insurance reimbursement to create favorable conditions for selling their products.

B. ***Europe***

Decision makers involved in the medical device procurement procedure in the European healthcare establishments

Decision makers involved in medical device procurement in healthcare establishments are similar in all the EU-5 countries. In Europe, evidence based purchasing is gaining momentum, but the major decision maker is the procurement groups or the healthcare professionals. The various decision makers involved are:

1. **Hospital purchasing department:** Takes purchasing decisions with inputs from physicians/nurses. Have a dual financing system – investments for certain facilities/equipment that are part of hospital plan and financed by the state, while consumables and other cost types have to be covered through DRG revenues.
2. **Physician/Nurse:** Are influencers in the decision making process or can propose, what medical devices could be beneficial.
3. **Procurement communities:** These are outsourced purchasing service providers. There are different kinds of procurement communities, which offer different

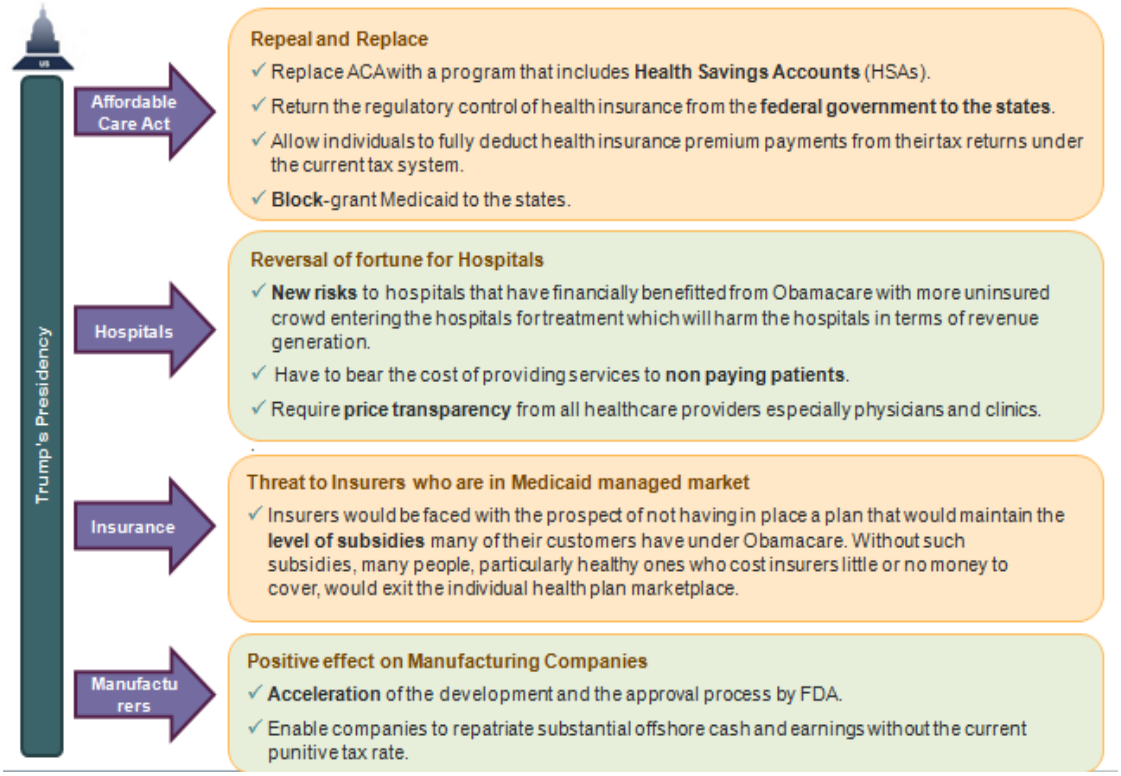
services. In general, procurement communities promise hospitals better pricing results. Special and complex products are still usually procured by hospitals directly.

4. **Medical device department:** Apart from maintenance function, advises the hospital purchasing department. Depending on the hospital, medical device departments also sometimes have a yearly budget for procurement of smaller investments.

4.4.4 Changing political scenario and reforms in both the geographies (U.S and Europe)

A. *USA*

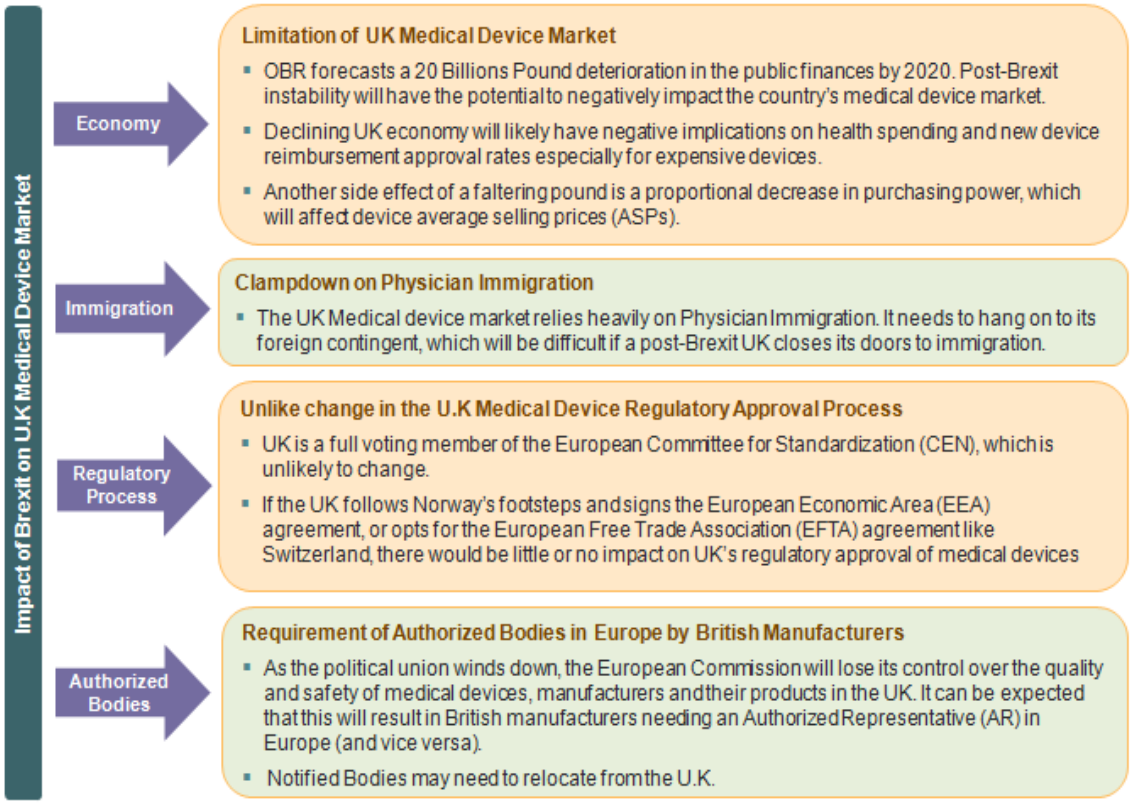
Effect of Trump's presidency on U.S healthcare



Source: Deloitte **Figure 4.45: Expected changes due to Trump's presidency**

B. *Europe*

Ripple effect of Brexit on European medical device market



Source: PWC **Figure 4.46: Expected changes due to application of Brxit**

5. Discussion and conclusion

5.1 Comparison of medical device approval systems in USA and Europe

Both in the USA and in Europe, strict legislation has been implemented to guarantee safe and effective availability of medical devices. On a broader level the market authorization procedures in both the geographies have the same basic concept. In both the systems, the endeavor to obtain market authorization increases with the perceived risk of the device and in both systems an existing equivalent device on the market allows for easier market authorization. Furthermore, easier market authorization can be attained if equivalence to an existing device on the market can be claimed. Also, in both the market authorization systems, market access for the lower risk medical device classes is the sole responsibility of the manufacturer. On the other hand, many striking differences between both the systems can also be identified. An important difference is that market authorization and approval process in the USA is granted and handled by the FDA, a governmental body thus, making the authorization process a governmental responsibility, while in Europe market authorization for medical devices is handled, designated and supervised by the authorities

referred as ‘Notified Bodies’. FDA has also explicitly pointed out that Notified Bodies operating in Europe are private companies, hinting that it is inferior to a governmental institution.

Additionally, in terms of technical requirements both the systems also differ. In Europe, harmonized European standards detailing technical specifications and requirements are an essential legislative tool for medical device manufacturers to establish conformity with the essential requirements. The European Commission does not partake in the development of the standards, they employ CEN consultants to check the accurateness of the Annexes in the standards. This gives European Commission some indirect influence on the market authorization process. On the contrary, in the USA recognized standards can be of national or international level. FDA is the body which participates in the development of the standards which forms the foundation for the market authorization. Thus, this gives FDA the power to directly influence the content of the standard and the process itself.

Also, the biggest debate of all has been that which system sanctions the most effective and safe medical devices to the market. Although FDA is high on clinical investigations on safety and clinical value, the downside is that it takes on an average two years longer to get a device approved in the USA. The negative implication of this approach is that a life saving is withheld from patients in the USA who are in dire need of it, whereas the same medical device is available to the European patients. This has alos led to US citizens going abroad to get a specific medical treatment. Also, from the manufacturers point of view, companies choose to first introduce their device in markets other than the USA and they even contemplate not introducing their devices in the US.

Another important parameter to consider in relation to the approval process for medical devices is the time it takes to bring a medical device in the market after successful completion of the pre-market requirements. For higher risk devices, clinical studies performed requires more time as compared to their low risk counterparts.

In terms of transparency, FDA makes most information related to market authorization and post-market activities publicly available, while such transparency has not yet been achieved in Europe and is an ongoing concept over there.

Comparative features of the approval system in both the geographies are illustrated in the following table:

System Feature	United States	European Union
Classification of medical devices	Based on risk factor classified into: Class I, II, III and HDE	Based on risk factor classified into: Class I, IIa, IIb, III
Central regulatory agency	Governmental agency namely, FDA	No
Market approval	Food and Drug Administration premarket approval must be obtained before marketing; once received, FDA approval permits the device to be marketed in the US	Conformité Européenne (CE) marking must be obtained before marketing the device; once received, CE marking permits the device to be marketed throughout the EU
Approval grantor	FDA	Competent authorities and Notified bodies, which are private sector, for profit companies located across the EU. Manufacturers may choose to use any notified body.
Data requirements	High risk devices are approved through the premarket approval (PMA) pathway. Moderate risk devices and some high risk devices can be marketed after getting "clearance" through the 510(k) pathway, ordinarily without any additional clinical data.	Generally, safety, performance, and reliability are tested. Clinical data are recommended for some high risk devices, but requirements vary across notified bodies. EU assessment provide less insight into clinical evidence as compared to USA

Registration of manufacturers	Manufacturers are required to register annually with the FDA.	Class I medical device manufacturers are required to register with notified bodies
Marking of the medical devices	No FDA approval/mark required for medical devices	Medical device legally placed should bear a CE mark
Time frame for approval	Ideally FDA requires 180 days for PMA and 90 days for 510(k) approval	Manufacturers can negotiate with the competent authroities to obtain authorization decision
Transparency	Proprietry limits with public reporting of premarketing review of approved devices, adverse events and recalls. Greater public access to evidence in the USA	Review done by notified bodies are not made public, postmarketing data only shared among competent authorities but not with public
Funding	Combination of federal appropriations (80%) and user fees (less than 20%)	Funding of competent authorities varys among countries, wherein Notified bodies are paid directly by sponsors
Patient Access	Premarketing clinical testing of high-risk devices delays patient access to these devices; however, there is no difference for low and moderate risk devices	EU patients may have sooner access to certain high-risk devices as compared to patients in the US

5.2 Comparison of patient access to medical devices in the US and Europe

Studies have shown that lower-risk devices achieve market access in a similar amount of time in both the United States and in Europe. However, the variation comes in term of the innovative and high-rish devices which require higher degree of clinical evidence and because of which the patient access time frame varies in the US and the Europe.

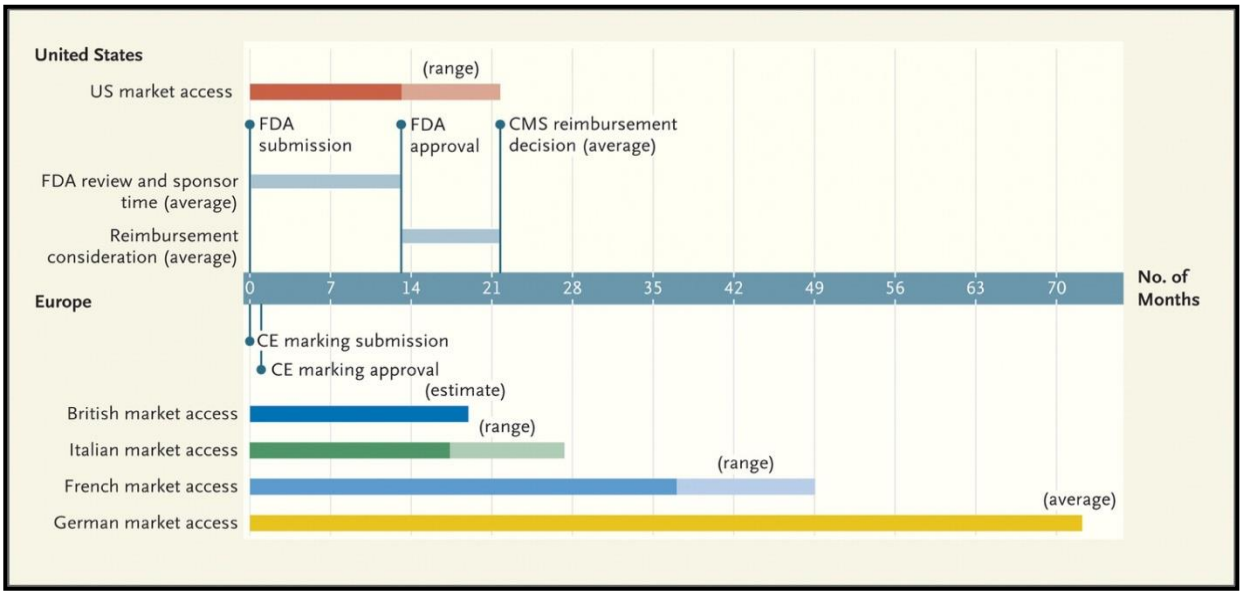
It is estimated that an average time of 13.1 months is taken to get the medical device available to the patients in the U.S where, 8.4 months are attributed for FDA review and the remaining 4.7 months is the time the agency waits for the sponsors to address deficiencies in the application, also reffered to as the ”sponsor time”. In US, CMS is the one who provides reimbursement for the majority of devices when they get FDA approved. For private insurers, the decisions regarding medical devices are made within a few weeks to a few months after FDA approval.

In Europe, the CE marking process is conducted by Notified bodies which are for profit, third party, accredited by the member state to assess device safety and performance. Though publicly available data is limited, anecdeotal information from notified bodies suggest that the whole process to take CE marking takes around 1-3 months, excluding sponsor time.

European patients do not have access to hig risk/innovative devices on receiving CE marking, each country must make a decision about reimbursement, a process that varies among different countries. Though the CE marking is granted based on fewer clinical evidence, the reimbursement process is on the contrary requires additional data on the device’s safety and effectiveness as well as on cost effectiveness..

Estimated vtime frames for the completion of the reimbursement process is 71.3 months is Germany, a range of 36 to 48 months in France, a range of 16.4 to 26.3 months in Italy and an estimated time period of 18 months in the U.K. For Spain, the time duration is not specified because the reimbursement process is highly decentralized and decision making occurs at the regional level.

Analyzing this information, it is determined that the time it takes to bring innovative, high risk devices in the U.S is similar to or shorter than the top 4 European countries taken into consideration. The CMS (public) system in the U.S takes approximately as long as those in Italy and the U.K, approximately half as long as that in France, and less than a third as long as that in Germany.



Source: The New England Journal of Medicine

Figure 47: Comparison of time frame for patient access in different countries

5.3 Comparison of medical device market and its components in both the US and the EU

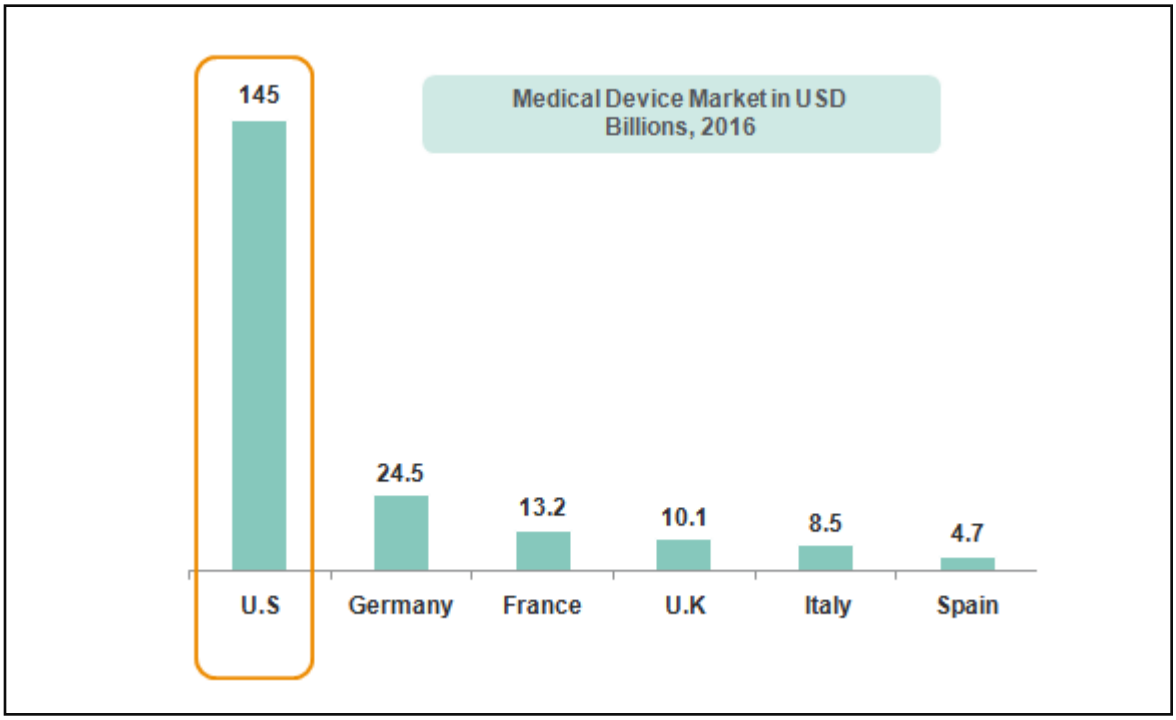


Figure 5.1: Medical device market, 2016

At present, U.S medical device market is pioneer globally and is expected to retain its position in the coming years. After U.S, Germany stands second globally with the market share of 24.5 Billions USD.

The top medical device companies in terms of revenue like Medtronic Inc., Johnson & Johnson, GE Healthcare, Cardinal Health, Becton Dickinson, etc. are all U.S based with their subsidiaries present across the globe.

On the other hand, Germany being the powerhouse of Europe also houses major brands like Philips Healthcare, Fresenius Medical Care, Siemens Healthcare and constitutes the major top medical device companies across the globe.

The industry barriers and drivers are almost similar across the geographies with the main focus points being the demographic shift to older population, medical-techno innovation in the field of healthcare and increased importance to quality of life.

In terms of export and import market for medical devices globally, the same trend is followed with U.S being the leader, followed by Germany, France, U.K, Italy and Spain.

Shifting dynamics in term of healthcare is observed in both the geographies with increased gravitation towards out-patient sector. With the introduction of incentive based healthcare reforms by the government, revolution is observed in the healthcare sector in terms of shifting of focus towards out-patient infrastructure with the introduction of ASC (Ambulatory Surgery Centers) in U.S and Europe.

Also, attention is being deviated towards long term healthcare facilities in the form of nursing homes, long term care facilities, hospices, etc. in both the US and Europe.

Moreover, political disturbance with Trump's presidency in the U.S and application of Brexit in Europe is also expected to affect the healthcare sector in both the geographies thereby, impacting the medical device sector as well. This dynamic political scenario can either prove to be favourable or unfavourable for medical device manufacturers trying to introduce new innovative medical devices or trying to gain entry in either of the territories.

Based on the facts and figures stated above, it is concluded that the medical device industry is assisting healthcare to reach new heights and improving the overall quality of healthcare across the globe. The two geographies which are dominating the medical device market and providing new insights and innovativeness in this field are the U.S and the European Union.

From manufacturers prospective, it is important to comprehend the similarities and differences between the both market systems in terms of market authorization and approval process, the current legislation, governmental involvement and technical requirements involved. Also, comparison in terms of patient access, i.e. the time when the medical device is made available to the patients after completion of the reimbursement process is of importance.

Thus, this study provides a comprehensive insight into the similarities and differences between both the systems and the impact of the emerging trends and administrative scenario on the medical device manufacturers.

6. Limitations

i. **Lack of information**: Due to non-comprehensive data production and registration of each country, there are certain limitations in terms of lack of data. The analysis has thus some weaknesses because of the lack of data, but a clear trend of medical device market and its effect could, however, be identified.

ii. **Confidentiality:** As per ZS policy, sharing any client information and data from paid sources and databases used by ZS is strictly forbidden and is considered grounds for immediate termination of employment. Several insights could have been added to this document and existing insights could have been further expanded upon in the absence of this policy. ZS confidentiality policy has not been violated in any way during the preparation and final presentation of this document.

iii. **Language barrier**: Many documents obtained from secondary search were in Turkish and had to be translated and verified against other sources for validity.

iv. **Secondary research**: As information and insights were obtained from secondary search, it is advisable to check for any updates, modifications or discontinuations to laws, systems, processes and stakeholders mentioned in this report before making any recommendations.

7. Ethical Considerations

This study is based on secondary/desk research and uses data from publicly available sources, thus, there are no associated ethical considerations for this study.

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