IIHMR UNIVERSITY

Thesis Presentation

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

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ZS

Index- Medical Devices

Introduction

About ZS Associates

ZS is the world's marketing and sales consultancy firm focused on the pharmaceutical and medical device industry majorly in the US and Europe. ZS delivers impact through its vast and varied expertise ranging from customer insights and strategy to analytics, operations and technology. ZS has 23 worldwide locations with over 4000 employees.

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 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

Aim

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

Materials and Methods

Materials and methods

- **Type of study:** Descriptive in nature

- **Study Design:** Systematic Review of Literature (Secondary Research)

- **Type of data:** Publicly available secondary research data sources were deployed like previous researches from various published sources and written submission from interested parties, statistics and information from government agencies like WHO, OECD, Eurostat, FDA; articles and reports from electronic databases like Research Gate, PubMed Central, BioMed Central, ScopeMed, Oxford Journals

- **Geographic Scope:** Two geographies namely the US and Europe are considered. In Europe, only EU-5 constituting Germany, France, United Kingdom, Italy and Spain are taken into account

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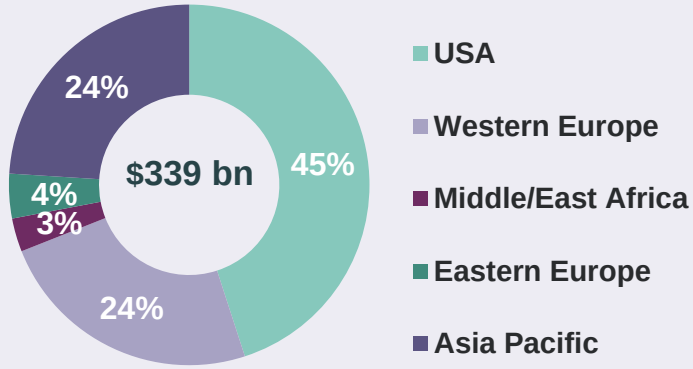
Overview of Medical Device Market

Global Medical Device Market, 2015



- The whole global medical device market size stands at nearly **$ 400 bn**
- U.S. medical device industry is the global leader with sales of around $145.948 billion, which represents approximately **45%** of the global market
- Europe standing second with the market share of **28%** followed by Asia Pacific (24%) and Africa (3%)
- The global medical technology industry is expected to blossom with a CAGR of **5.7%**

Industry Drivers

- **Up surging Healthcare Market:** Increasing global demand because of lifestyle diseases, ageing population and increasing strive to improve the quality of life.
- **Government Policy:** Government policymakers are seeking to create new and sustained opportunities for medical device market e.g. export and import
- **Medical-technical Innovation:** Unprecedented advancement in innovative and developed technologies, leading to growth in overall medical device industry.
- **Increasing demand for tele-health and home diagnostics products:** Healthcare institutes globally are demanding new healthcare products

Industry Barriers

Government Policy: Higher tax rates are imposed by the government on MDs manufacturers

- **Challenging Manufacturing Regulations:** Stringent regulations for device commercialization and distribution, trade (Export and Import), Dynamic and highly evolving nature of regulations make it difficult for the manufacturers.
- **Market Conditions:** Stringent labor laws, High operating costs.
- **Price pressures on medical device companies:** Different regulatory requirements, higher competition, reduced reimbursements, higher tariffs in different countries impact the sales of medical device companies

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Market Authorization of Medical Devices

Market authorization involves the entire comprehensive process from the development to the dissemination of medical devices in the market, : 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.

Market Authorization encompasses:

- Classification of Medical Devices
- Depending on the classification the market authorization procedure the medical device is subjected to
- Registration of manufacturers and medial devices
- Marking of Medical Devices
- Post marketing vigilance and surveillance

Note:

- 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

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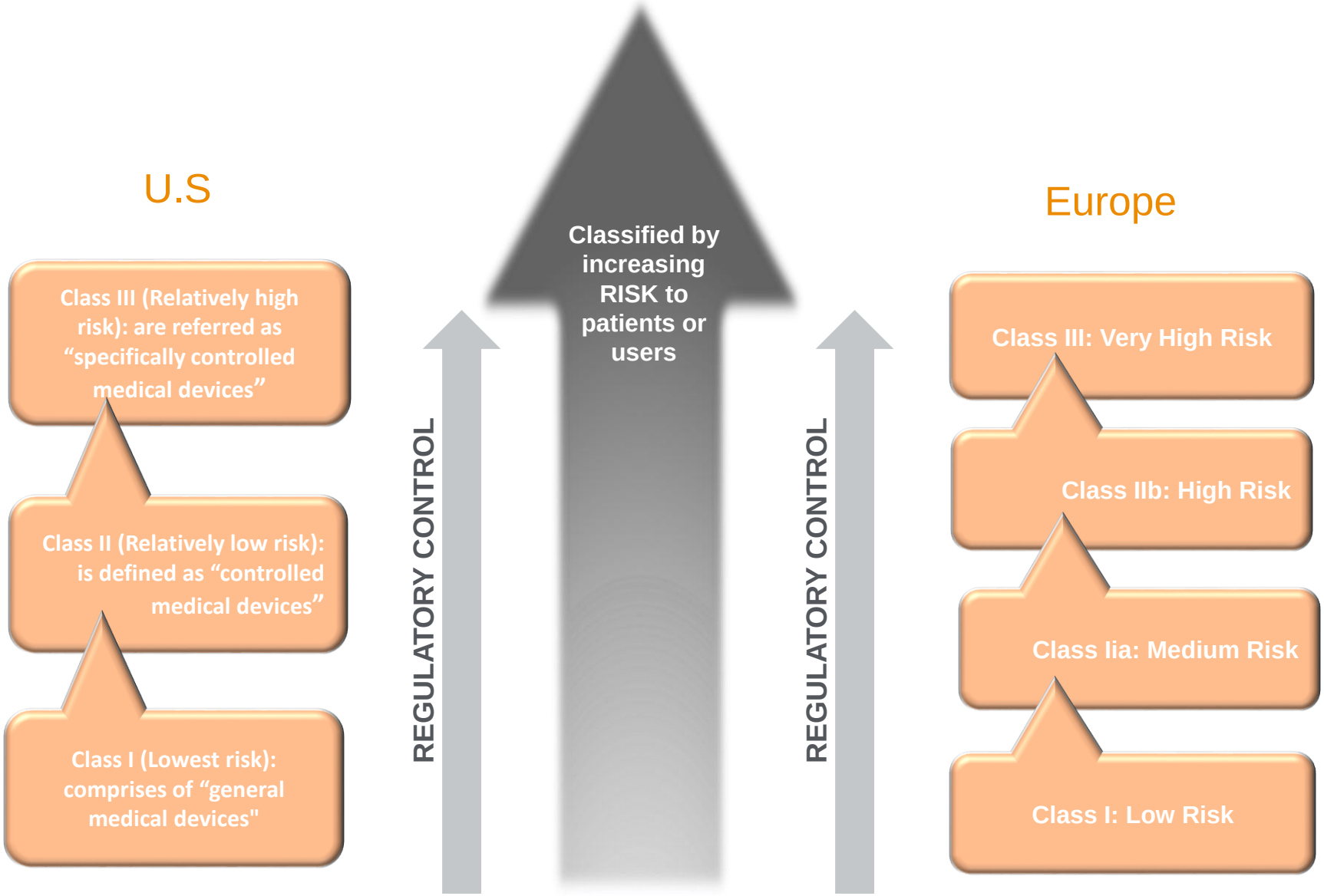
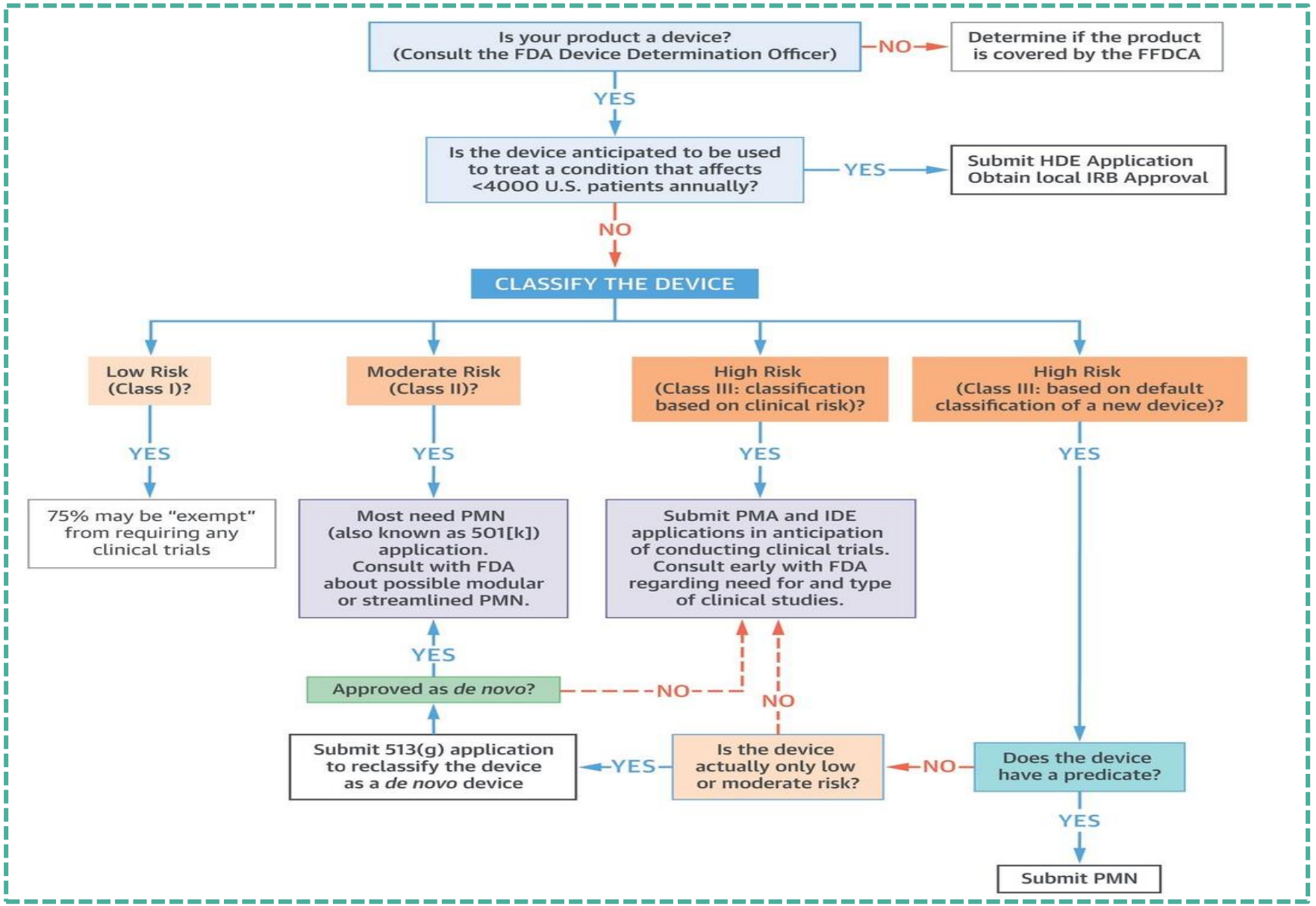
Classification of Medical Devices



Market Authorization Process in U.S as devised by FDA



Source: FDA

Market Authorization Process in Europe

From development to registration

	Safety (Technical Documentation)			Performance (Clinical Documentation)		
Class III	Development of Quality Management System	Risk Analysis and Risk Rating Rating of Biocomparability	Technical tests according to special norms	Clinical studies conducted; Ethic Commission	Analysis of clinical studies, preparation of clinical documentation	Notified bodies examine safety & performance
Class IIb			Technical tests according to special norms	Clinical evaluation based on clinical data/clinical examination		Notified bodies examine safety & performance
Class IIa			Technical tests and technical data	Clinical evaluation based on clinical data/clinical examination		Notified bodies examine safety & performance
Class I			Technical tests and technical data	Clinical evaluation based on suitable data		Companies examines safety & performance themselves

CE Mark

EU has directives related to medical device. These include:

- Active Implantable Medical Devices, AIMD, 90/76/EC
- Medical Devices Directives, MDD, 93/42/EEC
- In Vitro Diagnostic Medical Devices, IVDD, 98/79/E

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Comparison of Market Authorization Process

Comparative features of system in U.S & Europe

	U.S	Europe
Classification	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 Body	Governmental agency namely, FDA	No central regulatory body
Market Approval	FDA must grant PMA or 510 (K) before permitting the device to be marketed	CE marking must be obtained before marketing
Approval Grantor	FDA	Competent authorities and Notified bodies
Data Requirements	High risk devices are approved by PMA while medium risk devices require 510 (k) pathway and low risk devices are exempted	Clinical data is asked for high risk devices while low risk devices are exempted
Registration of manufacturers	Manufacturers are required to register annually with FDA	Class I medical device manufacturers are required to register
Marking of medical devices	No FDA approval mark required	Medical devices should bear a CE mark
Time frame for Approval	FDA requires 180 days for PMA & 90 days for 510 (k)	Manufacturers can negotiate with the competent authorities
Transparency	Greater public access to evidence in US	Reviews data not made public in Europe
Patient Access	Delay for high risk devices; no difference for low/medium risk devices	EU patients have earlier access to certain high risk devices

Patient Access and Reimbursement process

- 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

Key components of reimbursement

✓ **Coverage:** Defined as the payment criteria for a product, service or procedure
✓ **Coding:** Defined as the mechanism used for identification of a product, service or procedure
✓ **Payment:** Defined as the amount paid by the third party under the associated tariff

Regulatory bodies

Parameters	U.S	Germany	France	U.K	Italy	Spain
Technical Assessment	FDA, CDRH	BfArM , DIMDI,	HAS, CNEDiMTS, ANSM	MHRA, NICE	AGENAS, CUD, MoH	MSC, Instituto de salud carlos III
Reimbursement determining	FDA	SHI	MoH, CEPS, UNCAM	DH, NHS, CCG	ASR	Evaluators at regional level

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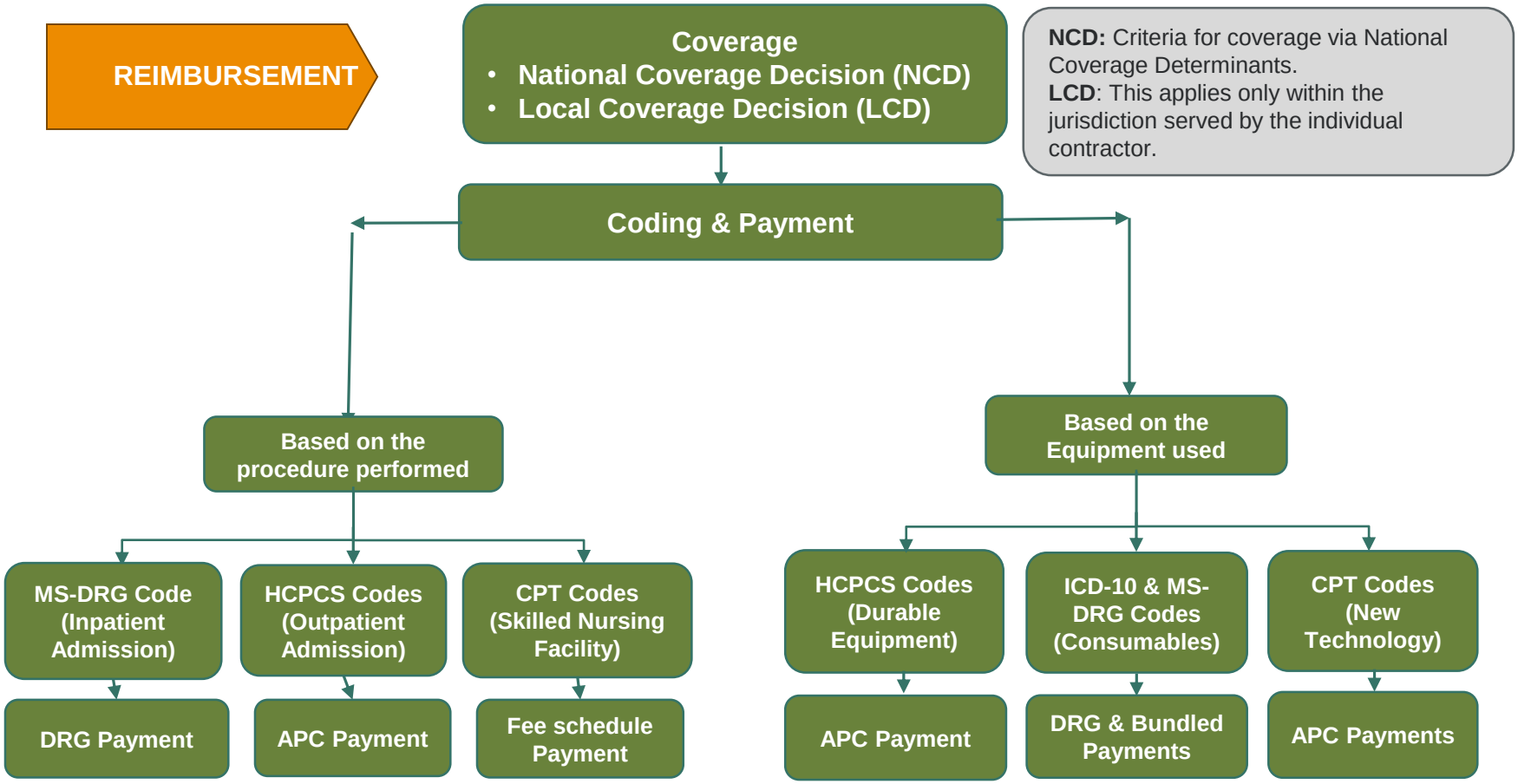
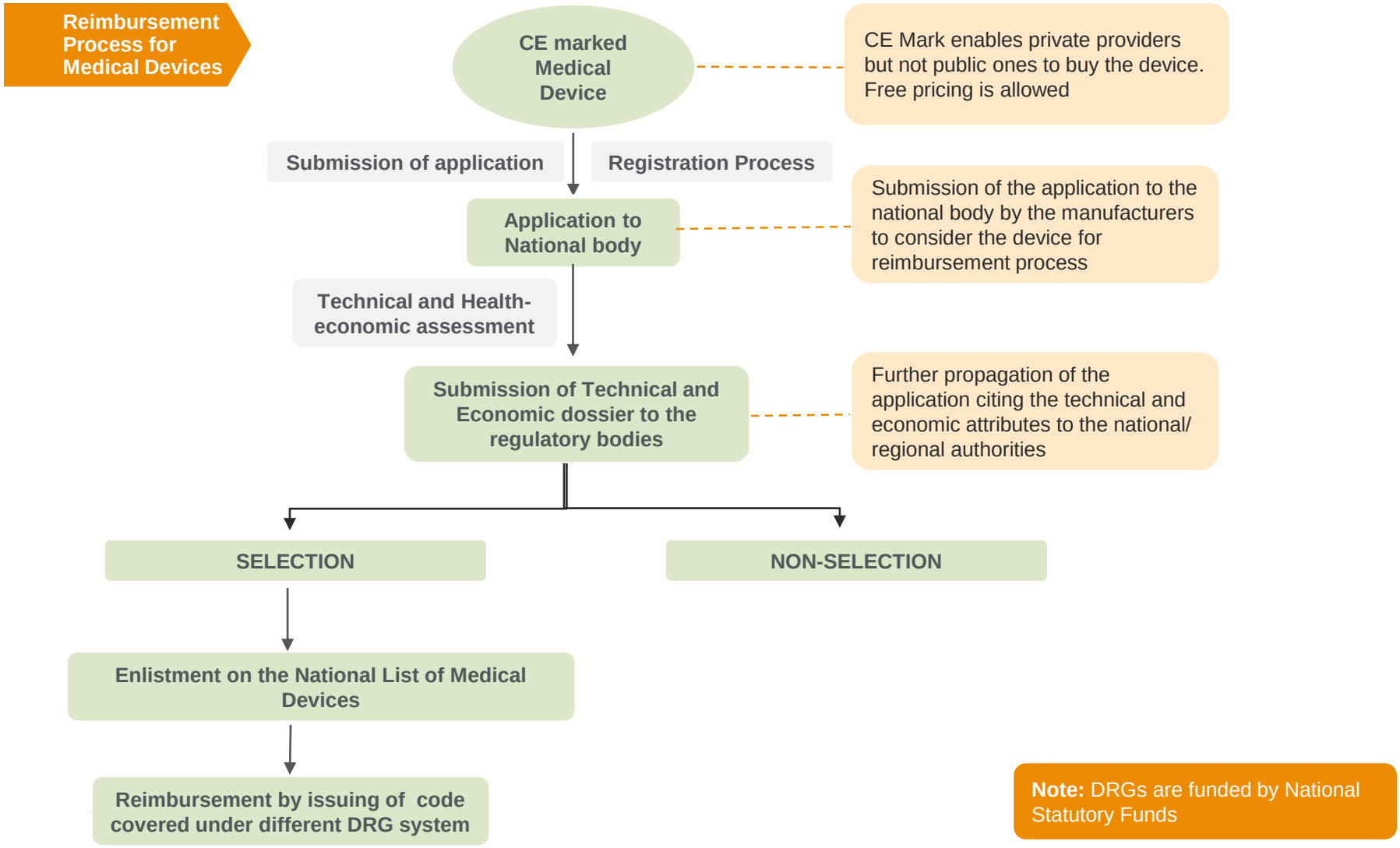
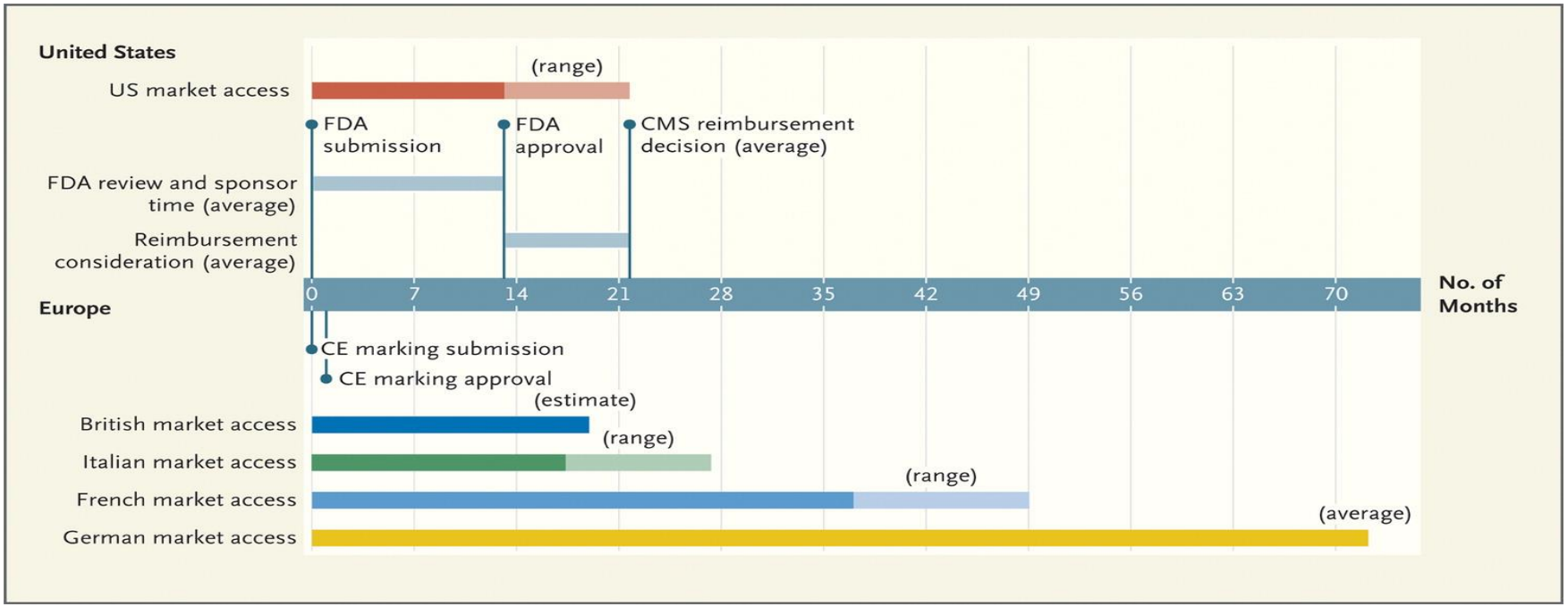
Reimbursement process in U.S



Reimbursement process in European Countries



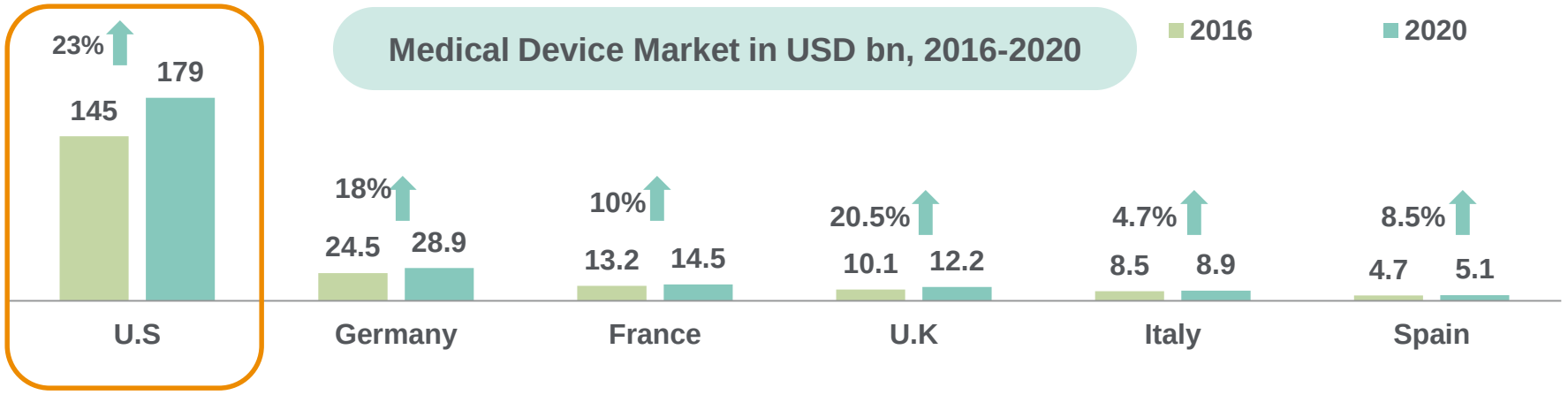
Comparison of reimbursement process time frame



Source: The New England Journal of Medicine

- Market access is achieved in similar time for low risk devices while different for high risk/innovative devices
- It takes around **13.1 months** to get the medical devices available to the patients in the U.S
- Time frames for the completion of the reimbursement process is **71.3 months** in Germany, a range of **36 to 48 months** in France**, 16.4 26.3 months** in Italy and an estimated time period of **18 months** in the U.K. For Spain, due to high decentralization in the reimbursement process the time frame estimation is not possible

Comparison of Medical Device Market



- At present, U.S medical device market is pioneer globally and is expected to retain its position in the coming years .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. 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

- After U.S, Germany stands second globally with the market share of 24.5 Billions USD. Germany also houses major companies like Philips Healthcare, Fresenius Medical Care, Siemens Healthcare

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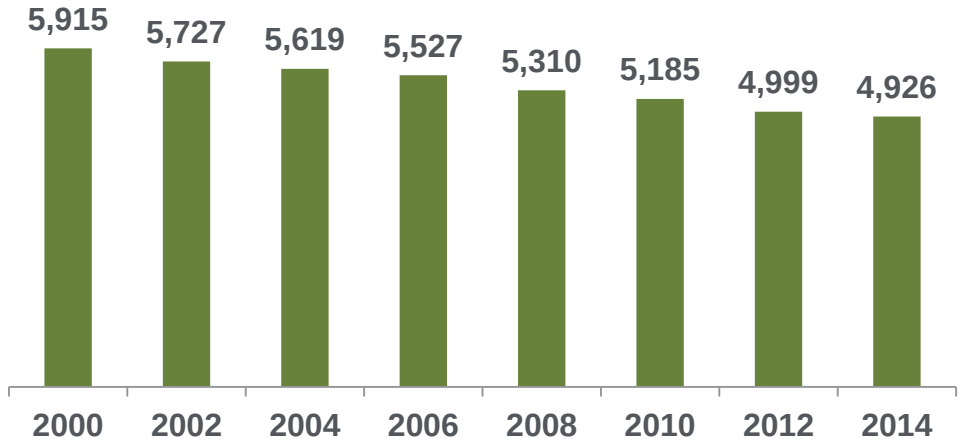
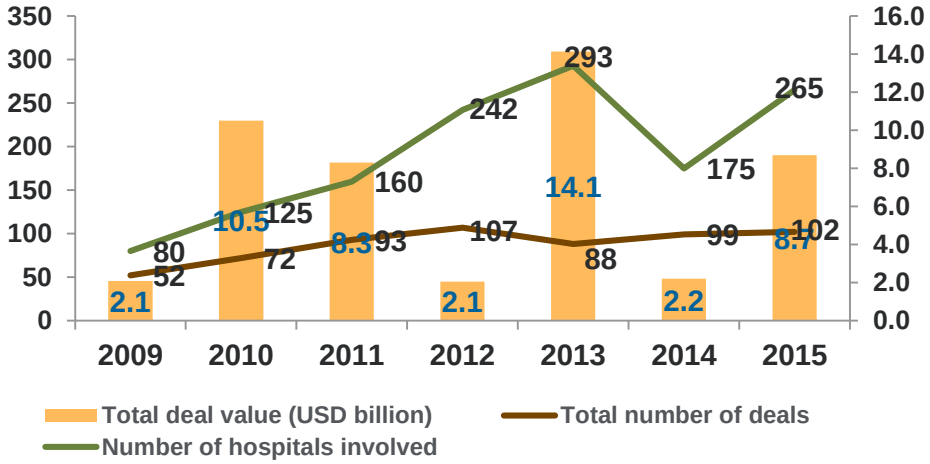
Changing dynamics of provider landscape in U.S

Number of U.S Hospitals, 2000-2014



- The Hospital industry 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.

US Hospitals M&A Deals, 2009-15



- Independent hospitals are confronting a period of rapid change by considering a variety of partnerships and collaborations 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 has resulted in better pricing results for medical devices due to increased negotiating power with the healthcare establishments

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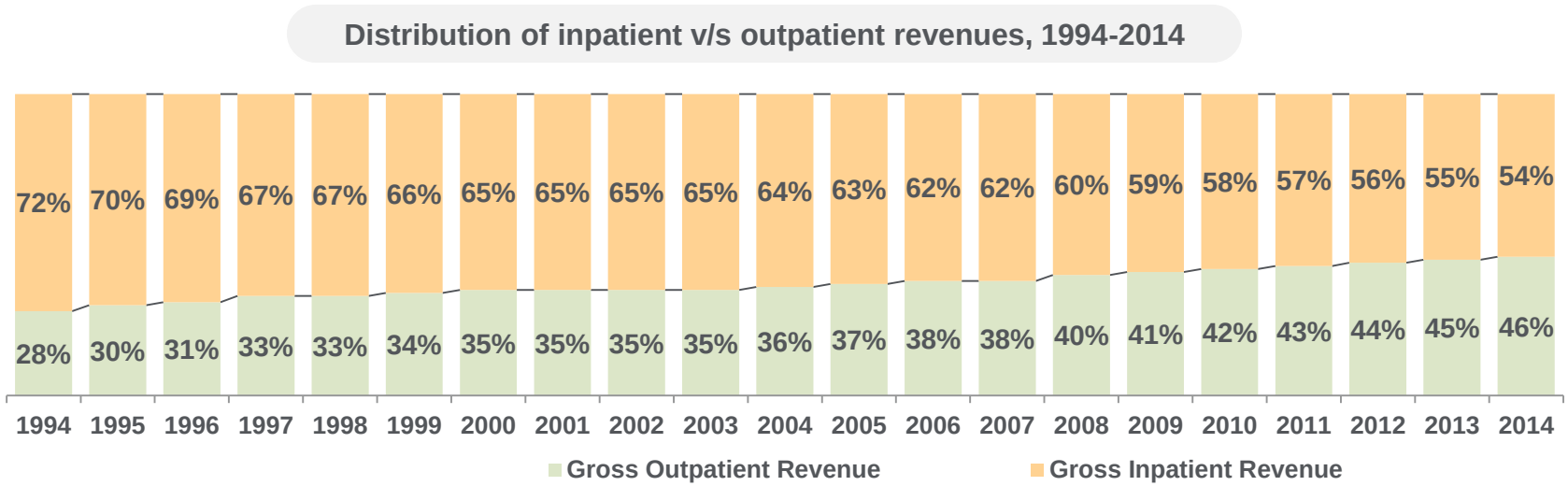
Resurgence in out-patient services in U.S Healthcare sector



Key Reasons for shift from In-patient to Out-patient Settings:

- Minimally invasive surgeries being favored in recent years
- Pricing pressure favoring low cost of outpatient settings due to low overheads
- More focus on Preventive Healthcare and keeping patients out of the Hospitals
- Due to favorable reimbursement rules and payment models for outpatient settings

This has resulted in creation of a new segment for the MD manufacturers, which is gaining popularity in the U.S healthcare industry

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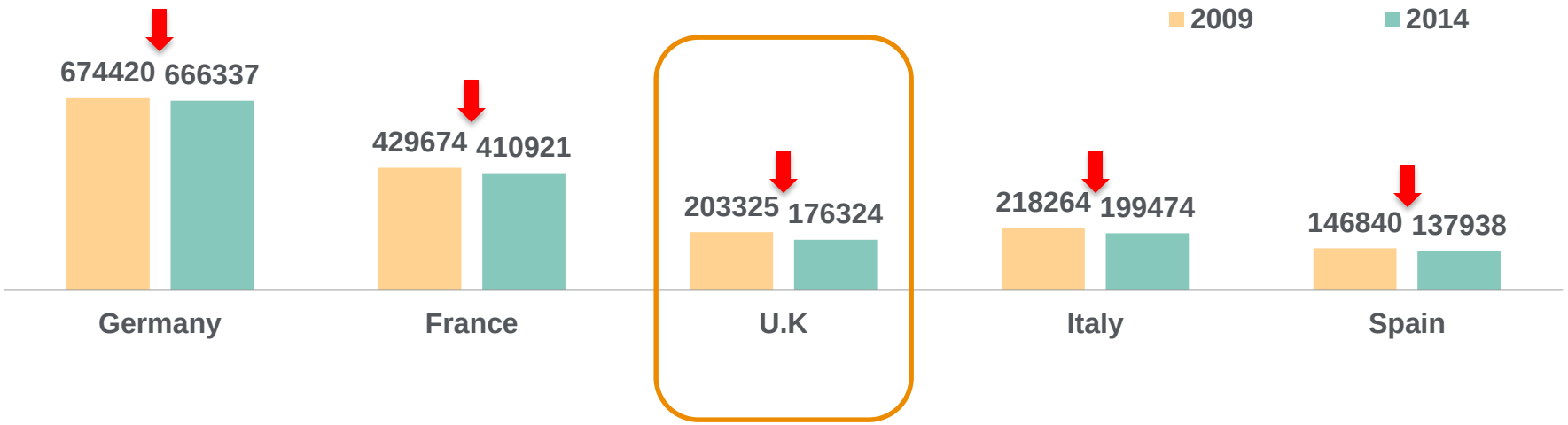
Dwindling of inpatient utilization and resources in European Healthcare



- In Europe, there has been observed a general trend of decrease in number of hospitals and hospital beds in recent years
- Amongst the EU-5 countries, U.K has shown the maximum decease in number of beds due to the application of policies and reforms
- This is accounted to the increasing importance of out-patient procedures and shift in admissions to day hospitals and ambulatory care
- As compared to U.S the shift of indices is slow, but this trend will gain momentum in the coming years

This has resulted in creation of a new segment for the MD manufacturers, which is gaining popularity in the European healthcare industry

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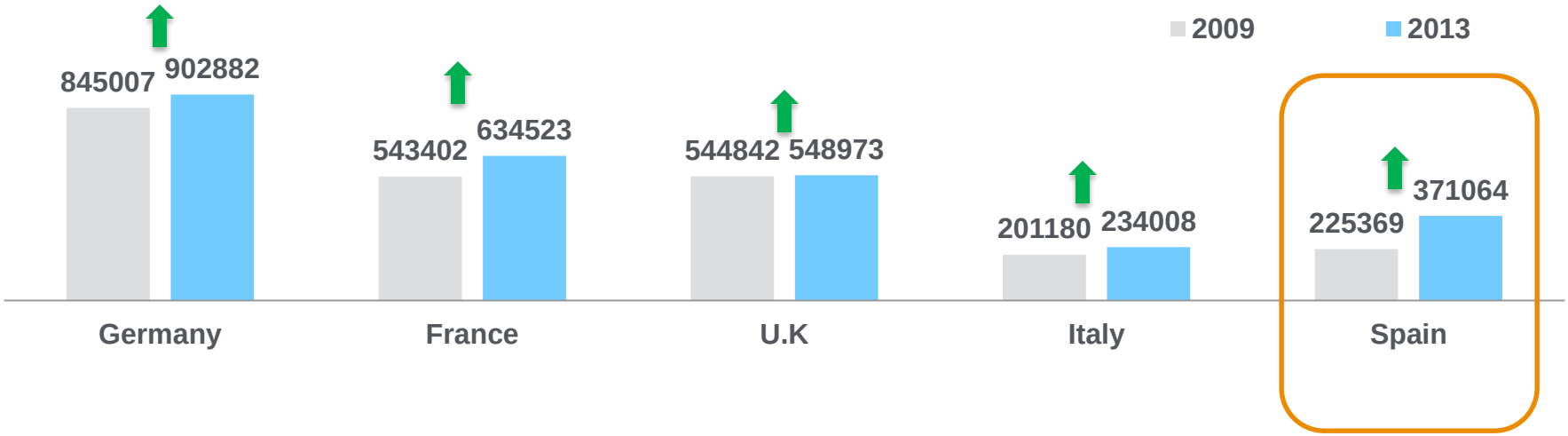
The market for long term healthcare facilities is flourishing in Europe

Beds in nursing and residential care facilities in EU-5, 2009 and 2014



- Long term care facilities like residential, semi-residential institutes and nursing homes provide long term elderly care, psychiatric care, terminal patient assistance, psychic disability assistance and physically handicapped assistance in Europe.
- Majorly it houses elderly population
- Amongst EU-5 countries, Spain has shown the maximum growth due to the increased number of long term health care facilities in recent years

This has resulted in creation of a new segment for the MD manufacturers, which is gaining popularity in the European healthcare industry

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Different influencers and decision makers are pitching in the hospital purchasing process of medical devices in U.S

Hospital based Analysis Committees

- Emergence of new reimbursement initiatives and strengthening of "value based purchasing" in hospitals has led to formation of analysis committees
- Formal committees like **"Value Analysis Committee", "Technology Analysis Committee"** have become an integral part and are becoming central in the decision making process for device procurement

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

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.

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In Europe, clinical evidence and robust data for MDs while procurement is gaining momentum

HCPs (Healthcare Professionals)

- Role of HCPs in the procurement process is to define the role of medical devices in therapeutic strategy and in evaluating the technical benefits of the medical devices being procured.
- They perform a very vital role in the procurement process for MDs

Procurement Committees/Groups:

- Several agencies are employed at regional and local level which help in procuring MDs by conducting technical and Health-economic assessment.
- In general, procurement communities promise hospitals **better pricing** results.

Hospital procurement department/Administration:

- This department headed by the Hospital administrator has a final say keeping in focus the financial, administrative and human management aspect of acquiring the MDs.
- Inputs are taken from all the stakeholders directly or indirectly involved

Trump's effect on Healthcare in U.S

Trump's Presidency

Affordable Care Act

Repeal and Replace

- ✓ Replace ACA with a program that includes **Health Savings Accounts** (HSAs)
- ✓ Return the regulatory control of health insurance from the **federal government to the states**
- ✓ Allow individuals to fully deduct health insurance premium payments from their tax returns under the current tax system

Hospitals

Reversal of fortune for Hospitals

- ✓ **New risks** to hospitals that have financially benefitted from Obamacare with more uninsured crowd entering the hospitals for treatment which will harm the hospitals in terms of revenue generation.
- ✓ Require **price transparency** from all healthcare providers especially physicians and clinics
- ✓ Accountable Care Organization (ACO's) formed under ACA will come under jeopardy

Insurance

Threat to Insurers who are in Medicaid managed market

- ✓ Insurers would be faced with the prospect of not having in place a plan that would maintain the **level of subsidies** many of their customers have under Obamacare. Without such subsidies, many people, particularly healthy ones who cost insurers little or no money to cover, would exit the individual health plan marketplace.

Manufacturers

Positive effect on Manufacturing Companies

- ✓ **Acceleration** of the development and the approval process by FDA.
- ✓ Enable companies to repatriate substantial offshore cash and earnings without the current punitive tax rate.

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Ripple effects of Brexit on U.K's Medical Device Industry

Impact of Brexit on U.K Medical Device Market

Economy

Limitation of UK Medical Device Market

- OBR forecasts a 20 Billions Pound deterioration in the public finances by 2020. Post-Brexit instability will have the potential to negatively impact the country's medical device market
- Declining UK economy will likely have negative implications on health spending and new device reimbursement approval rates especially for expensive devices
- Another side effect of a faltering pound is a proportional decrease in purchasing power, which will affect device average selling prices (ASPs)

Immigration

Clampdown on Physician Immigration

- The UK Medical device market relies heavily on Physician Immigration. It needs to hang on to its foreign contingent, which will be difficult if a post-Brexit UK closes its doors to immigration

Regulatory Process

Unlike change in the U.K Medical Device Regulatory Approval Process

- UK is a full voting member of the European Committee for Standardization (CEN), which is unlikely to change
- If the UK follows Norway's footsteps and signs the European Economic Area (EEA) agreement, or opts for the European Free Trade Association (EFTA) agreement like Switzerland, there would be little or no impact on UK's regulatory approval of medical devices

Authorized Bodies

Requirement of Authorized Bodies in Europe by British Manufacturers

- As the political union winds down, the European Commission will lose its control over the quality and safety of medical devices, manufacturers and their products in the UK. British manufacturers will need an Authorized Representative (AR) in Europe (and vice versa).
- Notified Bodies may need to relocate from the U.K.

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THANK YOU