


# MARKET ACCESS MEDICAL DEVICES

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MANAGING DIRECTOR

MEDICALPS, JUNE 27, 2019.



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## Who I am?

Corinne Lebourgeois, BSc, MBA  
Managing Director, MedC Partners

- > 25 years experience in medtech
- > 10 years working with the industry
- > 15 years working in the consulting business
- > Dedicated to innovation & start-ups
- > Board member with start-ups
- > Mentor at MassChallenge and Venture Lab

Mastering full product life cycle from R&D to market launch, reimbursement and negotiation with payers



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## What is market access ?

- A strategic asset
- Enabling companies to gain access to markets for products
- Convincing payers of the product value



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### What is market access ?

- MA for pharma includes
  - Pricing and Reimbursement (PR)
  - Health Economics and Outcome Research (HEOR),
- MA focuses on building economic models and Value Propositions.

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### Market Access for medtech

- New strategic element
- Started around 2005
- Becoming quite important since 2010

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### What are medical devices?



Implantables      In Vitro diagnostic (IVD) tests      Others

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### Differences medtech vs. drugs

Medtech	Drugs
<ul style="list-style-type: none"><li>• Duration: shorter dvpt time</li><li>• Investment: more modest</li><li>• 2 stages in clinical dvpt:<ol style="list-style-type: none"><li>1) Regulatory approval</li><li>2) Clinical effectiveness</li></ol></li><li>• Market access and reimbursement: relatively recent requirement</li></ul>	<ul style="list-style-type: none"><li>• Very long dvpt time ~15 years</li><li>• Investment: greater investment, perceived higher return on investment</li><li>• 1 big dvpt step<ul style="list-style-type: none"><li>➢ Clinical effectiveness must be demonstrated at the onset</li></ul></li><li>• Market access: has existed for the past 20 years</li></ul>

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### Medical device industry in EU

- Over **500 000 medical devices** and **in-vitro diagnostic tests** on the EU market
- Medtech industry employs over **500 000 people** in about **27 000 companies**, in majority start-ups or SMEs.
- 90% of SMEs, < 50 employees, generating revenue < 100 M €
- EU market: € 100 billions annual sales

Source: Conseil Européen

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## Today's context for device funding



- Countries are trying to limit their healthcare expenditure
- Austerity measures in place in many countries
- Healthcare system is one of the targets for cost crunching
  - Easier to pressure manufacturers than hospitals or doctors
- Hospitals have become profit centers
- Pressure to develop more and more sophisticated and costly devices to address complex health issues
- As a manufacturer, how do you introduce your products in a cost-contained market and how do you justify premium price?

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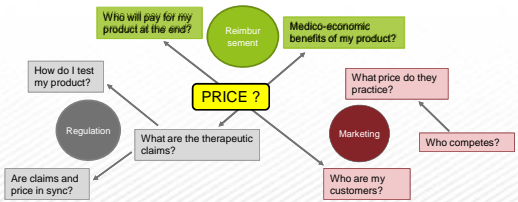
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## Where to start ?



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## Analyze your key parameters



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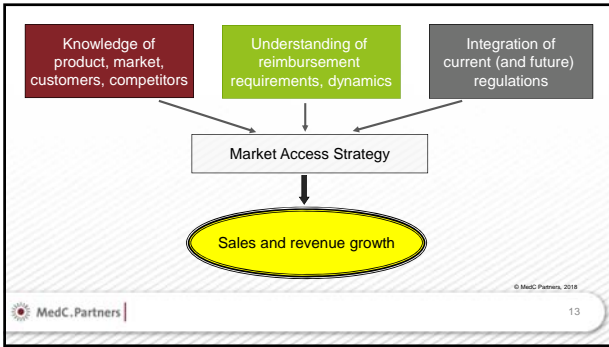
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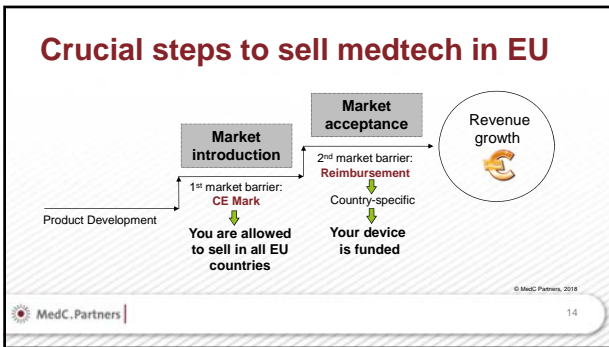
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### New MDR for CE mark

- Objective: improve safety and traceability
- Clinical evidence now required
- Mandatory registration of new technologies in Europe-wide database
- Reinforced role of Notified Bodies in controlling device's performance (mid- to high-risk medical devices)

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### Is CE Mark enough for a successful business in EU?

**Sometimes: Yes**

For devices addressing life-style and cosmetic needs, e.g.:

- Pregnancy tests
- Wrinkle filling
- Some dental implants

**Most of the time: NO**

For all other devices, e.g.:

- Cardiovascular implants
- Orthopedic prosthesis
- Genomic breast cancer tests

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**Reimbursement is necessary for a successful business**

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### With or without reimbursement?

**With reimbursement**  
Invest in clinical trials: demonstrate clinical effectiveness and medico-economic benefits

**Without reimbursement**  
Invest in marketing & communication



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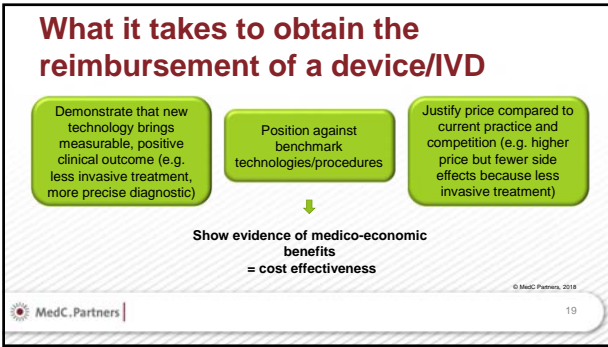
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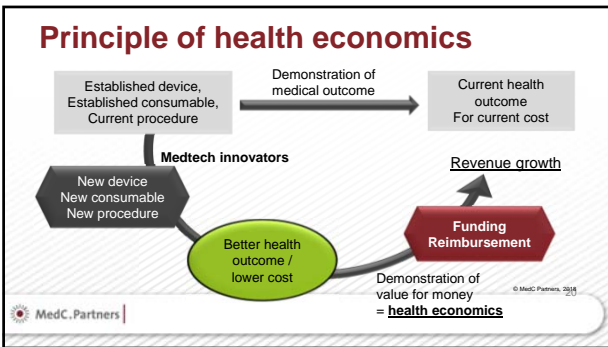
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### MedMAP: integrated strategy for market access

In which country will your device sell best?



What clinical indication is the most favorable to your device?

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### Optimal market access strategy with MedMAP

- A methodology developed to define where you will sell best
  - Which country ?
  - Which clinical application ?
- Assess reimbursement landscape and business opportunity for each of your options
- Develop your clinical strategy based on the understanding of market and reimbursement ecosystems
- Assess your risks before spending resources and focus on the highest business potential



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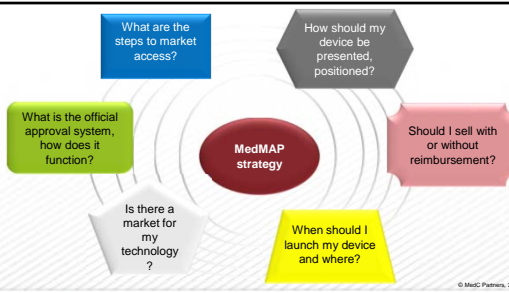
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## Common pitfalls for medtech manufacturers

- Launch of device with minimal clinical data and without cost effectiveness analysis
- Pricing without consideration for willingness to pay and budget
- Unclear guidance to ensure funding
- Focus exclusively on clinical benefits with payers
- Not explore alternative pricing models to overcome financial barriers
- Undisciplined price implementation in different countries
- Lack of knowledge of how a healthcare system integrates new technologies

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## Who we are

- Consulting firm dedicated to the medical device industry
- Founded in 2005 by Marie-Jose Moschetti and Corinne Lebourgeois
- One office in Geneva, another office in Paris
- Develops EU market access strategies for start-ups, SMEs, and corporations
- Performs business analysis and due diligence for financial groups

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## Our fields of expertise

- Cardiac surgery
- VAD (ventricular assist device)
- Interventional cardiology
- Peripheral vascular surgery
- Orthopedic
- Ophthalmology
- Interventional pneumonology
- Diabetes
- In vitro diagnostics (IVD)
- ENT (ear nose throat)
- Osteoporosis
- Gastroenterology
- Uro-gynecology



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## Our achievements

- **Reimbursement**  
Strategy, filing, submission, negotiations
- **Clinical**  
Clinical assessment, protocols, coherence with reimbursement strategy
- **Business**  
Marketing plan, business plan, project assessment, due diligence, market survey
- **Value pricing**  
Optimization of price within healthcare environment
- **Face-to-face meetings with experts**  
Authorities, payers
- **Interviews with healthcare stakeholders**  
Patients, doctors, payers
- **Regulatory**  
QA certification, CE marking, CE representative

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## Some publications



Clinica, Oct 2010

*In vivo*, Jun 2014

*Clinica, Medtech Insight*, Jun-Jul 2015

*In vivo*, Jun 2016

Market Access Know-how Keeps Strategic Medtechs Ahead of the Game

*In Vivo*, Nov 2018

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## Thank You

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DO YOU KNOW WHERE YOUR DEVICE WILL SELL BEST IN EUROPE?

MedC PARTNERS' Market Access Program

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